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PTO/SB/05 (4/98)

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. 4204.2C3

First Inventor or Application Identifier Michael A. Peshkin

Title See 1 in Addendum

Express Mail Label No. EL 350 465 915 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. Specification [Total Pages 45]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. Drawing(s) (35 U.S.C. 113) [Total Sheets 28]
4. Oath or Declaration [Total Pages 2]
 - a. Newly executed (original or copy)
 - b. Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
 - i. DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

NOTE FOR ITEMS 1 & 13 IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

5. Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - a. Computer Readable Copy
 - b. Paper Copy (identical to computer copy)
 - c. Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. Assignment Papers (cover sheet & document(s))
8. 37 C.F.R. § 3.73(b) Statement (when there is an assignee) Attorney
9. English Translation Document (if applicable)
10. Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS Citations
11. Preliminary Amendment
12. Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. * Small Entity Statement(s) Statement filed in prior application (PTO/SB/09-12) Status still proper and desired
14. Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. Other:

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

Continuation Divisional Continuation-in-part (CIP) of prior application No. 09/020,767

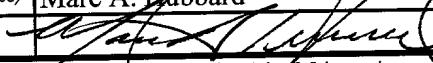
Prior application information: Examiner Bruce, D. Group / Art Unit: 2876

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

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Attachment to PTO/SB/05 (4/98) Utility Patent Application
Transmittal

1. Apparatus and Method for Planning a Sterotactic Surgical Procedure Using Coordinated Fluoroscopy

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: Unknown

Serial or Patent No.: 08/649,798

Attorney Docket No.: 6739-26640

Filing or Issue Date: May 17, 1996

Applicant or Patentee: Peshkin et al.

Invention: APPARATUS AND METHOD FOR PLANNING A STEREOTACTIC SURGICAL
PROCEDURE USING COORDINATED FLUOROSCOPY
VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9 (f) and 1.27 (d)) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION Northwestern University

ADDRESS OF ORGANIZATION 1801 Maple Avenue

Evanston, Illinois

TYPE OF ORGANIZATION

[X] University or other institution of higher education

[] Tax exempt under Internal Revenue Service Code (26 USC 501(a) and 501(c) (3))

[] Nonprofit scientific or educational under statute of state of The United States of America

(Name of state _____)

(Citation of statute _____)

[] Would qualify as tax exempt under Internal Revenue Service Code (26 USC 501(a) and 501(c) (3))
if located in The United States of America

[] Would qualify as nonprofit scientific or educational under statute of state of The United States of America
if located in The United States of America

(Name of state _____)

(Citation of statute _____)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9 (e) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code with regard to the invention entitled APPARATUS AND METHOD FOR PLANNING A STEREOTACTIC SURGICAL PROCEDURE by inventor(s) Michael A. Peshkin and Julio J. Santos-Munne described in

[] the specification filed herewith

[X] application serial no. 08/649,798, filed May 17, 1996

[] patent no. _____, issued _____

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9 (c) if that person had made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Indrani Mukharji

TITLE IN ORGANIZATION Director, Technology Transfer Program

ADDRESS OF PERSON SIGNING 1801 Maple Avenue

Evanston, IL 60201

SIGNATURE Indrani Mukharji

DATE July 15, 1996

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peshkin, Michael A., et al.

Title: Apparatus and Method for Planning
a Stereotactic Surgical Procedure
Using Coordinated Fluoroscopy

Express Mail Label No.
EL 350 465 915 US

BOX NON-FEE AMENDMENT
Assistant Commissioner for
Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Before calculation of the filing fee for, and examination of the referenced application, which is a continuation of Application No. 09/020,767, filed February 9, 1998, please enter the following amendments:

IN THE SPECIFICATION

Please insert at the beginning of the specification:

- - This is a continuation of application number 09/020,767, filed February 9, 1998, which is a continuation of application number 08/649,798 filed May 17, 1996, now U.S. Patent No. 5,799,055, which in turn is a continuation of application number 08/648,313 filed May 15, 1996. --

On page 12, line 1, replace "Fig.3c is a flow chart" with --Figs. 3C, 3D, 3E, and 3F are flow charts--.

On page 12, line 6, replace “Fig. 5 is a flow chart” with --Figs. 5A and 5B are flow charts--.

On page 12, line 9, replace “Fig. 6 is a flow chart” with --Figs. 6A and 6B are flow charts--.

On page 12, line 13, replace “Fig. 7 is a flow chart” with --Figs. 7A and 7B are flow charts--.

On page 13, line 4, replace “Fig. 16 is a flow chart” with --Figs. 16A and 16B are flow charts--.

On page 13, line 7, replace “Fig. 17 is a flow chart” with --Figs. 17A and 17B are flow charts--.

On page 13, line 11, replace “Fig. 18 is a flow chart” with --Figs. 18A and 18B are flow charts--.

On page 17, line 9, replace “Figs. 3c-18” with --Figs. 3C-18B--.

On page 17, line 13, replace “Figs. 4-18” with --Figs. 4-18B--.

On page 17, line 32, replace “Fig. 5” with --Fig. 5A--.

On page 17, line 35, replace “Fig. 6” with --Fig. 6A--.

On page 18, line 4, replace “Fig. 7” with --Fig. 7A--.

On page 19, line 2, replace “Fig. 16” with --Fig. 16A--.

On page 19, line 5, replace “Fig. 17” with --Fig. 17A--.

On page 19, line 12, replace “Fig. 18” with --Fig. 18A--.

On page 21, lines 2-3, replace “Fig. 5” with --Fig. 5A--.

On page 22, line 5, replace “Fig. 6” with --Fig. 6A--.

On page 22, line 5, replace "Fig. 6" with --Fig. 6A--.

On page 23, line 7, replace "Fig. 6" with --Fig. 6B--.

On page 23, line 12, replace "Fig. 6" with --Fig. 6A--.

On page 23, line 27, replace "Fig. 7" with --Fig. 7A--.

On page 25, line 20, replace "Fig. 6" with --Fig. 6A--.

On page 26, line 34, replace "Fig. 7" with --Fig. 7B--.

On page 32, line 9, replace "Fig. 16" with --Fig. 16A--.

On page 34, line 4, replace "Fig. 17" with --Fig. 17A--.

On page 35, line 31, replace "Fig. 18" with --Fig. 18A--.

IN THE CLAIMS

Please cancel claims 1 through 32.

-- 33. A computer-aided method for planning a surgical procedure comprising:

registering to a known coordinate frame a first two-dimensional, image of a

body's anatomy taken at a first observation angle;

displaying the first image; and

5 drawing in the displayed first image a representation of a surgical object to be placed in the body based the registration of the first image with the known coordinate frame.

34. The method of Claim 33 wherein drawing in the displayed first image the representation of the surgical object is in response to a user indicating at least one positioning parameter for the surgical object.

35. The method of Claim 34 wherein the at least one positioning parameter for the surgical object is defined in reference to the known coordinate frame.

36. The method of Claim 35 wherein the at least one parameter includes an approach angle of the surgical object.

37. The method of Claim 34 wherein the at least one parameter is defined in reference to the first image.

38. The method of Claim 37 wherein the at least one parameter includes a point in the body.

39. The method of Claim 37 wherein the user indicates the at least one parameter by positioning a cursor displayed within the first image.

40. The method of Claim 33 wherein a user indicates at least one parameter defining the surgical object.

41. The method of Claim 40 wherein the at least one parameter includes a dimension of the surgical object.

42. The method of Claim 33 further comprising:
registering to the known coordinate frame a second two-dimensional, image of the body's anatomy taken at a second observation angle;
displaying the second image; and

5 drawing in the displayed second image the representation of the surgical object based the registration of the second image with the known coordinate frame.

43. The method of Claim 42 wherein drawing the representation of the surgical object in the second image is in response to a user indicating on the displayed first image indicating a change in position of the representation of the surgical object in the first image.

44. The method of Claim 33, wherein the representation of the surgical object is a virtual guidewire defining, at least in part, a trajectory of insertion of the surgical object into the body.

45. The method of Claim 33, wherein the representation of the surgical object is a virtual guidewire having a length corresponding to a dimension of the surgical object to be inserted into the body.

46. The method of Claim 33 further comprising transmitting to a positioning mechanism coordinates for indicating the position of the surgical object represented in the first image.

47. The method of Claim 46 further comprising manipulating the positioning mechanism such that a guide coupled to the positioning mechanism is substantially aligned with the representation of the surgical object in the image.

48. The method of Claim 33 further comprising displaying information for indicating the position of the surgical object represented in the first image.

49. A computer readable storage medium encoded with instructions, which, when read by a computer, enable a computer to undertake a process comprising:

registering to a known coordinate frame a first two-dimensional, image of a body's anatomy taken at a first observation angle;

5 displaying the first image; and

drawing in the displayed first image a representation of a surgical object to be placed in the body based the registration of the first image with the known coordinate frame.

50. The computer readable storage medium of Claim 49 wherein drawing in the displayed first image the representation of the surgical object is in response to a user indicating at least one positioning parameter for the surgical object.

51. The computer readable storage medium of Claim 50 wherein the at least one positioning parameter for the surgical object is defined in reference to the known coordinate frame.

52. The computer readable storage medium of Claim 51, wherein the indication of the at least one positioning parameter is a reference on the displayed first image controlled by a user.

53. The computer readable storage medium of Claim 49 wherein the process further comprises:

registering to the known coordinate frame a second two-dimensional, image of the body's anatomy taken at a second observation angle;

5 displaying the second image; and

drawing in the displayed second image the representation of the surgical object based the registration of the second image with the known coordinate frame.

54. The computer readable storage medium of Claim 53 wherein drawing the representation of the surgical object in the second image is in response to an input received from a user indicating a position of the surgical object.

55. The computer readable storage medium of Claim 53 wherein drawing the representation of the surgical object in the second image is in response to an input received from a user indicating a position of the representation of the surgical object in the displayed first image.

56. The computer readable storage medium of Claim 53 wherein drawing the representation of the surgical object in the second image is in response to an input indicating a change in position of the representation of the surgical object in the first image.

57. The computer readable storage medium of Claim 53 wherein registering to the known coordinate frame the first image and the second image includes registering known coordinates of a plurality of fiducials within the reference frame with positions of the plurality of fiducials in the first and second images.

58. A computer-aided method for planning a surgical procedure comprising:

registering a first two-dimensional, image of a body's anatomy taken at a first observation angle with a second two-dimensional image of the body's anatomy taken at a second observation angle;

5 displaying the first image;

 drawing within the displayed first image drawing within the displayed first image a representation of a surgical object to be placed in the body based on an input indicating a position of the surgical object;

 displaying the second image; and

10 drawing in the displayed second image the representation of the surgical object.

59. The method of Claim 58 wherein drawing the representation of the surgical object in the second image is based, at least in part, on positioning in the displayed first image of the representation of the surgical object in the first image.

60. The method of Claim 58 wherein drawing in the first image and drawing second image the representation the surgical object is at least in part in response to a user indicating at least one positioning parameter for the surgical object.

61. The method of Claim 60 wherein the at least one positioning parameter for the surgical object is defined in reference to a known coordinate frame to which the first and the second images are registered.

62. The method of Claim 60 wherein the at least one parameter includes an approach angle of the surgical object.

63. The method of Claim 60 wherein the at least one parameter includes a point in the body.

64. The method of Claim 60 wherein the user indicates the at least one parameter by positioning a reference displayed within the first or second images.

65. The method of Claim 58 wherein a user indicates at least one parameter defining the surgical object.

66. The method of Claim 58 further comprising transmitting to a positioning mechanism coordinates for indicating the position of the surgical object represented in the first image.

67. The method of Claim 66 further comprising manipulating the positioning mechanism such that a guide coupled to the positioning mechanism is substantially aligned with the representation of the surgical object in the image.

68. The method of Claim 58 further comprising displaying information for indicating the position within a known coordinate frame of reference for the surgical object for use in manually positioning a guide.

69. The method of Claim 58 wherein registering the first and second images includes registering a plurality of fiducials having known coordinates within a known coordinate frame of reference with images of the plurality of fiducials within in the respective first and second images.

70. A computer readable storage medium encoded with instructions, which, when read by a computer, enable a computer to undertake a process comprising:

receiving a first two-dimensional, image taken of a patient's body and a plurality of radio-opaque fiducials placed adjacent the body at known positions; and

registering the image by optimizing parameters of a known geometric model such that projections of the plurality of fiducials into the first image best fit positions of the plurality of fiducials in the image.

71. The computer readable storage medium of Claim 70, wherein the process further comprises:

receiving a second, two-dimensional image taken of the patient's body and the plurality of fiducials from a position different from the first image; and

5 registering the second image by optimizing parameters of the known geometric model such that projections of the plurality of fiducials into the second image best fit positions of the plurality of fiducials in the second image.

72. The computer readable storage medium of Claim 71, wherein the process further comprises:

receiving input indicating on one of the first and second images a position of a representation of an imaginary object with respect to the body; and

5 drawing on the other of the first and second images a corresponding representation of the imaginary object projected into said other of the first and second images.

73. The computer readable storage medium of Claim 72 further comprising:

receiving input indicating a change to a second position of the representation of the imaginary object within said one of the first and second image; and

5 redrawing within said other of the first and the second images the corresponding representation of imaginary object in the second position.

74. The computer readable storage medium of Claim 72 wherein the imaginary object is a representation of a surgical object and the corresponding representation is also of the same surgical object.

75. The computer readable storage medium of Claim 71, wherein the process further comprises:

receiving an input indicating a position of an imaginary object within the body;

and

5 drawing on the first and the second images a representation of the imaginary object in the indicated position.

76. The computer readable storage medium of Claim 75, wherein the process further comprises:

receiving an input indicating a change in the position of the imaginary object to a second position; and

5 redrawing in the first and the second images the representation of imaginary object in the second position.

77. The computer readable storage medium of Claim 70, wherein registering the image further comprises:

displaying the image; and

5 receiving an input from a user indicating on the image the position of each of the plurality of fiducials within the image.

78. The computer readable storage medium of Claim 70, wherein the process further comprises linearizing the image before registering the image.

79. A method comprising:

receiving a first two-dimensional, image taken of a patient's body and a plurality of radio-opaque fiducials placed adjacent the body at known positions; and

registering the image by optimizing parameters of a known geometric model such
5 that projections of the plurality of fiducials into the first image best fit positions of the plurality of fiducials in the image.

80. The method of Claim 79 further comprising:

receiving a second, two-dimensional image taken of the patient's body and the plurality of fiducials from a position different from the first image; and

registering the second image by optimizing parameters of the known geometric
5 model such that projections of the plurality of fiducials into the second image best fit positions of the plurality of fiducials in the second image.

81. The method of Claim 80 further comprising:

receiving input indicating on one of the first and second images a position of a representation of an imaginary object with respect to the body; and

drawing on the other of the first and second images a corresponding
5 representation of the imaginary object projected into said other of the first and second images.

82. The method of Claim 81 further comprising:
receiving input indicating a change to a second position of the representation of
the imaginary object within said one of the first and second image; and
redrawing within said other of the first and the second images the corresponding
representation of imaginary object in the second position.

83. The method of 81 wherein the imaginary object is a representation of a
surgical object and the corresponding representation is also of the same surgical object.

84. The method of Claim 80 further comprising:
receiving an input indicating a position of an imaginary object within the body;
and
drawing on the first and the second images a representation of the imaginary
object in the indicated position.

85. The method of Claim 84 further comprising:
receiving an input indicating a change in the position of the imaginary object to a
second position; and
redrawing in the first and the second images the representation of imaginary
object in the second position.

86. The method of Claim 79 further comprising:
displaying the image; and
receiving an input from a user indicating on the image the position of each of the plurality of fiducials within the image.

87. The method of Claim 79 further comprising linearizing the image before registering the image. –

REMARKS

Should he be of any assistance, the examiner is invited to telephone the undersigned attorney at (214) 855-7571.

Please charge any fees due in connection with this paper to Deposit Account No. 13-4900 of Munsch Hardt Kopf & Harr, P.C. A duplicate copy of this paper is enclosed.

Respectfully submitted,



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PATENT APPLICATION
of
Michael A. Peshkin
and
Julio J. Santos-Munné
for
**APPARATUS AND METHOD FOR PLANNING A
STEREOTACTIC SURGICAL PROCEDURE
USING COORDINATED FLUOROSCOPY**
(Attorney Docket: 6739-26640)

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APPARATUS AND METHOD FOR PLANNING A
STEREOTACTIC SURGICAL PROCEDURE
USING COORDINATED FLUOROSCOPY

5 Background and Summary of the Invention

The present invention relates to an apparatus and method for planning and guiding insertion of an object along a linear trajectory into a body. More particularly, the present invention relates to an apparatus and method 10 for coordinating two captured fluoroscope images to permit effective three-dimensional planning of the trajectory using only two-dimensional images.

Numerous medical interventions involve placing a needle, drill, screw, nail, wire or other device in the 15 body. In some cases the angle and position of the device are both of critical importance, for example in the drilling of a hole for a screw along the axis of a spinal pedicle. In other cases, it is primarily the positioning of the end-point of the device which is important, for 20 example in placing a biopsy needle into a suspected tumor. In still other cases, the objective is only to define a point rather than a line, for example in targeting a tumor for radiation therapy. Many other examples exist, especially in the field of orthopaedics.

25 The present invention is also relevant to the development of percutaneous technique. Executing a linear trajectory for the insertion of instrumentation into the body through the skin is more difficult than open surgical technique, but the reduced invasiveness and trauma of 30 percutaneous placement makes it desirable.

Fluoroscopy is frequently used by surgeons to assist medical procedures. Continuous fluoroscopy during a surgical procedure is undesirable because it exposes the surgeon's hands to radiation. Furthermore, regardless of 35 whether intermittent or continuous fluoroscopy is used, the

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resulting images are two-dimensional while insertion of the surgical instrument requires three-dimensional awareness by the surgeon.

The apparatus and method of the present invention involve acquisition and storage of two separate fluoroscopic images of the body, taken from two different angles. Typically, although not necessarily, these would be an anterior/posterior (A/P) image taken front-to-back of the patient, and a sagittal image taken side-to-side. These two fluoroscopic images are displayed on two adjacent computer monitors. The surgeon uses a trackball or other computer input device to specify on the monitors an insertion point and an insertion trajectory.

A mechanical positioning device is then used to position a guide through which the surgeon performs the insertion of the surgical instrument. The positioning device may either be an active computer controlled manipulator such as a robot, or it may be a manually adjusted mechanical device which is set numerically in accordance with an output from the computer.

The apparatus and method of the present invention establish the projective geometric relationships relating each of two acquired fluoroscopic images to the three-dimensional workspace around and within the patient's body, despite essentially arbitrary positioning of the fluoroscope. The two images then become a coordinated pair, which permits three-dimensional planning that might otherwise be expected to require a computed tomography (CT) scan.

While the acquisition and display of two approximately orthogonal images may be expected to present the surgeon with the greatest ability to plan in three dimensions, two images are not strictly necessary. It is possible to use a single captured image for some procedures, particularly if the surgeon has adjusted the

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beam axis of the fluoroscope into alignment with the intended trajectory. Furthermore, more than two images could also be acquired and coordinated, should that be advantageous.

5 Several other approaches to stereotactic or robotic surgery, planned on a computer screen displaying medical images, have been described by other workers, and will be listed below. Some background is given here before discussing prior art. The method and apparatus of the
10 present invention constitute a technique we call coordinated fluoroscopy. Coordinated fluoroscopy is a technique for REGISTRATION and for SURGICAL PLANNING. It allows registration based on the acquired fluoroscopic images themselves, without requiring any additional
15 measuring devices. It allows three-dimensional surgical planning based on fluoroscopic views from two angles, without requiring three-dimensional imaging such as computed tomography (CT), and without requiring that the two fluoroscopic images be acquired from orthogonal
20 fluoroscope poses.

REGISTRATION

Registration is a key step in any image-guided surgical system. Registration is the determination of the
25 correspondence between points of the image upon which a surgical plan is prepared, and points of the workspace in the vicinity of (and within) the patient. If a numerically controlled tool (whether robotic or manual) is to be used, the coordinate system of that device must also be brought
30 into registry with the image.

It is common to accomplish registration with the help of a global positioning device, usually optical, which can measure the three-dimensional coordinates of markers placed anywhere over a large volume of space. Coordinated
35 fluoroscopy avoids the necessity for this expensive and

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inconvenient device, instead deriving registration directly from the acquired fluoroscopic images themselves.

Coordinated fluoroscopy uses a "registration artifact" which is held in a fixed position relative to the patient
5 while one or more fluoroscopic images are acquired from different angles (poses). There is no need to constrain the fluoroscope poses at which these various images are acquired, for instance to require that they be orthogonal, nor is there a need to instrument the fluoroscope so that
10 the pose angles can be measured. Instead, pose information is extracted after-the-fact from the images. It is a substantial benefit of the present invention that surgeons can acquire fluoroscopic images using fluoroscope poses of their own choosing, as they are accustomed.

15 The registration artifact contains a plurality of features (fiducials) which are designed to be easily identifiable on a fluoroscopic image. The embodiment described here uses eight small steel spheres embedded in a radiolucent matrix. The positions of these fiducials are
20 known relative to a coordinate system fixed in the artifact, either by design or by measurement.

From the two-dimensional locations of the projections of these fiducials in a fluoroscopic image, we can determine the geometric projections that carry a
25 general three dimensional point anywhere in the vicinity of the artifact into a projected point on the image. This establishes registration between image and workspace. Several images can each be registered relative to the same registration artifact, thus also bringing all the images
30 into registry with one another.

Identification of the geometric projections, as discussed above, would not be possible with raw fluoroscope images, which are highly nonlinear and distorted. It is necessary first to map and compensate for these
35 distortions. It is useful to be aware of the necessity of

distortion compensation when comparing the present invention to prior art.

SURGICAL PLANNING

5 Surgical planning is also a key step in image-guided surgery. Planning of three-dimensional surgical procedures might be expected to be done on a three-dimensional dataset, such as can be reconstructed from computed tomography (CT) data. However, surgeons are
10 accustomed to planning on two-dimensional images:

radiographs or fluoroscopic images. Indeed even when CT data is available, planning is usually done on individual two-dimensional CT "slices" rather than on a
15 three-dimensional reconstruction.

15 The coordinates of the endpoints of a line segment representing an intended screw, biopsy needle, or drilled hole are of course three-dimensional, as are the coordinates of a single point within the body marking the present location of a tumor or a fragment of shrapnel. In
20 surgical planning such points can be specified on a
25 two-dimensional image, or on each of several two-dimensional images. Each such two-dimensional image is
30 a projection of the same three-dimensional space.

It is necessary to convert the two-dimensional
25 coordinates of specified points on each of several images into a three-dimensional coordinate which can be used to guide a tool along a desired trajectory or to a desired
30 point within the body. To do so one must have knowledge of the geometric relationship of the projections that created
35 the images.

In the absence of such geometric knowledge a point specified on one image and a point independently specified on another image may in fact not correspond to any single point within the body. This is so because a
35 point specified on a two-dimensional image is the

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projection of a LINE in space. The implied point in three-dimensions is the intersection of two such lines, one implied by the point specified on each image. Two such lines created independently may be skew, intersecting nowhere. Similarly, line segments for an intended procedure can not be chosen independently on two images, otherwise they will in general not correspond to a well-defined three-dimensional line segment.

In coordinated fluoroscopy, the geometric projections that relate the two images to a single three-dimensional coordinate system are established before planning commences. The points chosen by the surgeon on two (or more) images can therefore be constrained by the software such that they DO correspond to a well-defined point in three-dimensions. In practice, as a surgeon adjusts an intended point or line segment on one image, the point or line segment displayed on the other image(s) continuously updates and adjusts as well. One cannot draw "arbitrary" points or line segments independently on the images; the software only allows one to draw points or line segments that correspond to a well-defined point or line segment in three-dimensions.

The benefits of planning on geometrically coordinated images as described above are threefold:

- 25 1) Once the surgeon has selected a point or a line segment on two images, the three-dimensional point or line segment to which the selections correspond is fully defined and ready to be executed.
- 30 2) An axial view such as could be attained from a CT slice is generally unattainable fluoroscopically. The angle that is most easily visualized in axial view, known as the transverse angle, is therefore difficult to select or execute under fluoroscopy. In coordinated fluoroscopy the transverse angle is implicitly specified by the surgeon by selecting line segments on two images. This may assist

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the surgeon in visualizing and planning the transverse angle for a procedure.

3) In conventional fluoroscopy, image dilation due to beam divergence is of unknown extent, making
5 accurate measurement of anatomic distances difficult. In coordinated fluoroscopy the actual in-situ length of an intended line segment can be determined by the software. This is useful for selecting appropriate screw length, as well as for other purposes.

10

BACKGROUND

Lavalle et al. in Grenoble, France have developed a system for spinal surgery which uses computed tomography as an image source. The CT data is assembled into a
15 three-dimensional data set which can then be resliced at will on orthogonal planes. Surgical planning proceeds on three mutually orthogonal planes simultaneously. Registration is performed by using an optical tracking device to digitize arbitrary surface points of the
20 vertebrae, and matches those surface points to the CT data set.

Nolte et al. in Bern, Switzerland have developed a very similar spinal system to Lavalle et al. Registration differs in that the optical tracking device is
25 used to digitize specific anatomic landmarks rather than general surface contours. The features are then pointed out manually in CT data, allowing a match to be made.

P. Finlay in High Wycombe, England has developed a fluoroscopic system for head-of-femur (hip) fractures.
30 Accuracy requirements in this procedure are not very great, so fluoroscope distortion compensation is not needed. Its absence also precludes identification of the geometric projections from images as is done in the present invention. Instead, the two fluoroscope poses are required
35 to be orthogonal and the C-arm must not be moved along the

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floor in between the two images. Registration is accomplished by noting various features of a surgical tool which appears in the images, and by highlighting a marker wire which also appears in the field of view of the
5 fluoroscope.

Potamianos et al. in London, England have developed a system for kidney biopsy and similar soft-tissue procedures. It incorporates a digitizing mechanical arm to which a biopsy needle is attached, and
10 which can be moved about manually by the surgeon. Surgical planning per se is absent; instead a line segment representing the present position of needle is displayed superimposed upon captured (static) fluoroscope images, as the needle is moved manually near and within the patient.
15

Phillips et al. in Hull, England have developed a system for orthopaedic procedures. It uses a optical tracking device as well as a fluoroscope. Registration is accomplished by instrumenting the fluoroscope with light emitting diodes and tracking them with the optical tracker.
20 Surgical planning software is specific to the surgical procedure, and tends to offer medical opinion rather than just display a trajectory as in the present invention. For intramedullary nail placement, for instance, the surgeon outlines target holes in an intramedullary prosthetic, and
25 software calculates a trajectory through them.

U.S. Patent 4,750,487 (Zanetti) describes a stereotactic frame which overlays a patient. A single anterior/posterior fluorograph is then acquired, in which a crosshairs affixed to the frame is visible. By measuring
30 the displacement of the crosshairs from the desired target, a motion of the frame can be accomplished which brings the two into alignment. This invention does not facilitate three-dimensional stereotaxy as does the present invention.

U.S. Patent 5,078,140 (Kwoh) describes a stereotactic and robotic system for neurosurgery. It uses CT images.

5 ASPECTS OF THE INVENTION

According to the present invention, a method is provided for planning a stereotactic surgical procedure for a linear trajectory insertion of surgical instrumentation into a body using a fluoroscope for generating images of the body. The method includes placing adjacent to the body a registration artifact containing a plurality of fiducials; displaying on a computer monitor an image of the patient's body and the registration artifact; receiving a user or automatic algorithmic input to identify two-dimensional coordinates of the fiducials of the registration artifact displayed on the first monitor; and registering the image by creating a geometric model having parameters, said model projecting three-dimensional coordinates into image points, and numerically optimizing the parameters of the geometric model such that the projections of the known three-dimensional coordinates of the fiducials best fit the identified two-dimensional coordinates in the image.

The method further includes displaying on a second computer monitor a second image, taken of the patient's body and the registration artifact but from an angle different from that of the first image, and receiving a user or automatic algorithmic input to identify two-dimensional coordinates of the fiducials displayed on the second computer monitor; and registering the second image by creating a geometric model having parameters, said model projecting three-dimensional coordinates into image points, and numerically optimizing the parameters of the geometric model such that the projections of the known

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three-dimensional coordinates of the fiducials best fit the identified two-dimensional coordinates in the second image.

The method, whether one or two images have been acquired, further includes the step of receiving a user input to select on a computer monitor an entry point for a surgical instrument. In the case of two images, also receiving a user input to select on a computer monitor the position, length, and angles of a virtual guidewire representing the trajectory for the surgical instrument; and drawing a segment, to be known as a PROJECTED GUIDEWIRE, on the image(s). When there are two images, the projected guidewires are constrained to correspond geometrically to the same three-dimensional segment in space, to be known as the VIRTUAL GUIDEWIRE.

The method further includes receiving a user input to move either end of a projected guidewire, by revising the virtual guidewire of which the projected guidewire(s) are projections, and by redrawing the projected guidewires in correspondence with the revised virtual guidewire.

The method further includes receiving a user input to change the length of the virtual guidewire, and redrawing the projected guidewire(s) in correspondence with the revised virtual guidewire. A special case is that the length is zero, so that what is planned is a virtual targetpoint rather than a virtual guidewire.

The method further includes receiving a user input to change the sagittal, transverse, or coronal angle(s) of the virtual guidewire, updating the orientation of the virtual guidewire based on the new angles, and redrawing the projected guidewire(s) in correspondence with the revised virtual guidewire.

The method further includes producing an output to adjust the coordinates of a tool guide such that the projection of the axis of the guide in an image is brought

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into correspondence with the entry point displayed on the computer monitor.

The method further includes producing an output to adjust the coordinates of a tool guide such that it is brought into correspondence with the virtual guidewire; or producing an output to adjust the coordinates of a tool guide such that the position of the guide along its axis is offset by a preselected distance from one endpoint of the virtual guidewire, in order to control the location within the body of the surgical instrument to be inserted.

The method further includes transmitting said coordinates to a robot or other automatic mechanical device, or displaying said coordinates such that human operator may manually adjust a mechanical device.

15

Brief Description of the Drawings

The detailed description particularly refers to the accompanying figures in which:

Fig. 1 is a diagrammatic illustration of the stereotactic surgical apparatus of the present invention for coordinating images from a fluoroscope, planning a linear trajectory medical intervention, and controlling a robot to control the linear trajectory medical intervention;

25 Fig. 2 is a perspective view of a registration artifact and tool guide of the present invention;

Fig. 3a is a sample screen display of the user interface which includes an anterior/posterior (A/P) taken by the fluoroscope and displayed on a first computer monitor along with a number of the buttons and entry fields necessary to run the program;

30 Fig. 3b is a sample screen display which includes a sagittal image taken by the fluoroscope and displayed on a second computer monitor along with a number of the buttons and entry fields necessary to run the program;

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Fig. 3c is a flow chart of the steps performed by the computer during a main program loop;

Fig. 4 is a flow chart illustrating the steps performed by the computer to acquire an A/P image from the
5 fluoroscope;

Fig. 5 is a flow chart illustrating the steps performed by the computer to acquire a sagittal image from the fluoroscope;

Fig. 6 is a flow chart illustrating the steps
10 performed by the computer and the user to select or identify A/P fiducials from the A/P image displayed in Fig.
3a;

Fig. 7 is a flow chart of the steps performed by the computer and the user to select or identify sagittal
15 fiducials displayed on the sagittal image of Fig. 3b;

Fig. 8 is a flow chart illustrating the steps performed by the computer to register the A/P image;

Fig. 9 is a flow chart illustrating the steps
20 performed by the computer to register the sagittal image;

Fig. 10 is a flow chart illustrating the steps
performed by the computer for changing a transverse angle
of the virtual guidewire;

Fig. 11 is a flow chart illustrating the steps
performed by the computer to change the length of the
25 virtual guidewire used in the stereotactic surgical
procedure;

Fig. 12 is a flow chart illustrating the steps performed by the computer to change a sagittal angle of the
virtual guidewire;

Fig. 13 is a flow chart illustrating the steps
performed by the computer to change the approach angle of
the robot;

Fig. 14 is a flow chart illustrating the steps
performed by the computer to move the robot illustrated in
35 Fig. 1 to the planned position and orientation;

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Fig. 15 is a flow chart illustrating the steps performed by the computer to move the end effector of the robot along the axis of the tool guide;

Fig. 16 is a flow chart illustrating the steps 5 performed by the computer when the computer receives a user input based on a cursor in the A/P image area of Fig. 3a;

Fig. 17 is a flow chart illustrating the steps performed by the computer when the computer receives a user input based on a cursor in the sagittal image area in Fig.

10 3b; and

Fig. 18 is a flow chart illustrating the steps performed by the computer when the computer receives a user input based on a cursor in the robot control areas of Figs. 3a-b.

15

Detailed Description of Drawings

Referring now to the drawings, Fig. 1 illustrates the stereotactic system 10 for linear trajectory medical interventions using calibrated and coordinated fluoroscopy.

20 The apparatus and method of the present invention is designed to utilize images from a fluoroscope 12 such as a standard C-arm which generates fluoroscopic or x-ray images of a body on a surgical table 14. The imaging arm 16 is moveable so that both anterior/posterior (A/P) and sagittal 25 or side images of the body can be taken.

A robot 18 is situated adjacent the surgical table 14. Illustratively, the robot is a PUMA-560 robot. The robot 18 includes a movable arm assembly 20 having an end flange 22. An alignment or registration artifact 24 is 30 coupled to the end flange 22 of robot 18.

The registration artifact 24 is best illustrated in Fig. 2. The artifact 24 is X-ray and visually transparent with the exception of 8 opaque spheres or fiducials 26, and an aperture 30 to hold a tool guide 28 35 through the artifact 24. Initially, the artifact 24 is

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positioned roughly over the area of interest of body 32 and within the field of view of the fluoroscope 16. Therefore, the fiducials 26 show up as distinct dots on the A/P and sagittal images as discussed below. The shape of the
5 artifact is designed so that the image dots from the fiducials 26 will not overlap each other and is sensitive to any angular deviations. The robot arm 20 can adjust the artifact 24 in three-dimensions about X-axis 34, Y-axis 36, or Z-axis 38 illustrated in Fig. 1.

10 The coordinated fluoroscopic control system of the present invention is controlled by computer 40, which includes a microprocessor 42, and internal RAM 44, and a hard disk drive 46. Computer 40 is coupled to two separate graphics monitors 48 and 50. The first graphics monitor 48
15 displays a sagittal image taken by the C-arm 12. The second monitor 50 displays an A/P image taken by the C-arm 12. Computer 40 further includes a serial communication port 52 which is coupled to a controller 53 of robot 18. Computer 40 is also coupled to C-arm 12 for receiving the
20 images from the C-arm 12 through an image acquisition card
• 54. Computer 40 is also coupled to an input device 56 which is illustratively a keyboard having a track ball input control 58. Track ball input 58 controls a cursor on both monitor 48, 50.

25 The displays on monitors 48 and 50 are illustrated in Figs. 3a and 3b. Referring now to Fig. 3b, the sagittal image is displayed in area 62 on monitor 48. All eight fiducials 26 should appear in the sagittal image area 62. If not, the artifact 24 or the C-arm 12 should be
30 adjusted. As discussed in detailed below, computer 40 displays a top entry point 64 and a bottom point 66 of a projected guidewire 68. The projected guidewire 68 is a line segment which is displayed on the sagittal image area representing the position of the instrumentation to be
35 inserted during the stereotactic surgical procedure. A

line of sight 70 is also displayed in the sagittal image area 62.

Various user option buttons are displayed on monitor 48. The surgeon or operator can access these options by moving the cursor to the buttons and clicking or by selecting the appropriate function keys (F1, F2, etc.) on the keyboard. The option buttons displayed on monitor 48 include button 72 (function F2) for acquiring the sagittal image, button 74 (F4) for selecting sagittal fiducials, and button 76 (F6) for registering the sagittal image. In addition, button 78 (F10) is provided for setting the sagittal angle, button 80 (F8) is provided for setting the screw length, and button 82 (F12) is provided for moving the robot along an axis of the tool guide. Finally, the display screen includes a robot control area 84. The operator can move the cursor and click in the robot control area 84 to control robot 18 as discussed below.

Referring to Fig. 3a, the A/P image displayed on the display screen of monitor 50 is illustrated. The A/P image is displayed in area 86 of the screen. Again, all eight fiducials 26 should appear within the A/P image area 86. The top insertion point of the virtual guidewire is illustrated at location 88, and the bottom point is located at location 90. The projection of the guidewire onto the A/P image is illustrated by line segment 92.

Computer 40 also displays various option buttons on monitor 50. Button 94 (F1) is provided for acquiring the A/P image. Button 96 (F3) is provided for selecting the A/P fiducials. Button 98 (F5) is provided for registering the AP image. Button 100 (F7) is provided for setting a transverse angle of the virtual guidewire, and button 102 (F9) is provided for setting an approach angle for the robot. Button 104 (F11) is provided for moving the robot. Computer 40 also displays a robot control area 84.

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The operator can move the cursor and click in the robot control area 84 to control robot 18 as discussed in detail below.

The present invention allows the surgeon to
5 select the point of entry for the surgical instrument by
moving the top point of the projected guidewire 88 in the
A/P image area 86. The operator can also adjust the bottom
point of the projected guidewire 90 to specify the
transverse and sagittal angle. In addition, the operator
10 can adjust the top point of the projected guidewire 64 to
specify the position on the line of sight and bottom point
of the projected guidewire 66 to specify the sagittal and
transverse angle in the sagittal image area 62. Therefore,
15 the surgeon can select the desired position and orientation
of the surgical instrument into the body.

The computer 40 is programmed with software to
correct spatial distortions from the optics of the
fluoroscope 12. The system of the present invention
permits effective three-dimensional planning of the
20 stereotactic surgical procedure using only a pair of two
dimensional fluorographic images displayed on the adjacent
monitors 48 and 50. It is not required to use a CT slice
in order to fully specify the location of the surgical
instrument. The computer 40 establishes the direct
25 geometric relationship between the A/P and sagittal images,
despite image distortions and the essentially random or
free-hand positioning of the C-arm 12, to establish the A/P
and sagittal images. The improved system of the present
invention can establish this exact geometric relationship
30 within sub-millimeter accuracy.

Once the sagittal and A/P images are registered,
points or lines chosen by the surgeon on one of the A/P
image or the sagittal image are immediately displayed by
computer 40 as corresponding projections on the other
35 image. Therefore, using the sagittal image on monitor 48

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and the A/P image on monitor 50, the surgeon can stereotactically plan the linear trajectory without the requirement of CT scan slice. Accordingly, the procedure of the present invention can be performed without the very 5 expensive CT scan devices which can cost in excess of \$1 million.

Details of the operation of the software for controlling the system of the present invention are illustrated in Figs. 3c-18.

10 All of the notations, subscripts and mathematical formulae, equations, and explanations are included in the attached Appendix. Throughout the flow charts described Figs. 4-18, reference will be made to the Appendix and to the numbered Sections [1] through [15] set forth in the 15 Appendix.

The main program begins at block 110 of Fig. 3c. Computer 40 creates a parent window at block 112 and then draws buttons on a main window as illustrated at block 114. Computer 40 then creates a sagittal child window on monitor 20 48 as illustrated at block 116. Computer 40 also creates an A/P child window on monitor 50 as illustrated at block 118. Computer 40 then determines whether a button or key has been pressed at block 120. If not, computer 20 waits as illustrated at block 122 and then returns to block 120 25 to wait for a button or key to be pressed.

If a button or key was pressed at block 120, computer 40 determines whether the Acquire A/P Image button 94 or the F1 key was pressed at block 124. If so, computer 40 advances to block 166 of Fig. 4. If not, computer 40 30 determines whether the Acquire Sagittal Image button 94 or the F2 key was pressed at block 126. If so, the computer 40 advances to block 200 of Fig. 5. If not, computer 40 determines whether the Select A/P Fiducial button 96 or the F3 key was pressed at block 128. If so, computer 40 35 advances to block 234 of Fig. 6. If button 96 or the F3 key

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was not pressed at block 128, computer 40 determines whether the Select Sagittal Fiducial button 74 or the F4 key was selected as illustrated at block 130. If so, computer 40 advances to block 276 of Fig. 7. If not, 5 computer 40 advances to block 132.

In block 132, computer 40 determines whether the Register A/P Image button 98 or the F5 key was pressed. If so, computer 40 advances to block 324 of Fig. 8. If not, computer 40 determines whether the Register Sagittal Image 10 button 76 or the F6 was pressed as illustrated at block 134. If so, computer 40 advances to block 350 of Fig. 9. If not, computer 40 advances to block 136.

From block 136, computer 40 determines whether the Transverse Angle button 100 or the F7 key was pressed 15 as illustrated at block 138. If so, computer 40 advances to block 376 of Fig. 10. If not, computer 40 determines whether the screw Length button 80 or F8 key was pressed as illustrated at block 140. If so, computer 40 advances to block 388 of Fig. 11. If not, computer 40 determines 20 whether the Sagittal Angle button 78 or the F10 key was pressed as illustrated at block 142. If so, computer 40 advances to block 400 of Fig. 12. If not, computer 40 determines whether the Approach Angle button 102 or the F9 key was pressed as illustrated at block 144. If so, 25 computer 40 advances to block 412 of Fig. 13. If not, computer 40 advances to block 146.

In block 146, computer 40 determines whether the Move Robot button 104 or the F11 key was pressed. If so, computer 40 advances to block 422 of Fig. 14. If not, 30 computer 40 determines whether the Move Robot Along Axis button 82 or the F12 key was pressed as illustrated at block 148. If so, computer 40 advances to block 452 of Fig. 15. If not, computer 40 determines whether the A/P Image area of monitor 50 has been selected by clicking when 35 the cursor is in the A/P image area 86 as illustrated at

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block 150. If so, computer 40 advances to block 476 of Fig. 16. If not, computer 40 then determines whether the Sagittal Image area was selected by positioning the cursor in the sagittal image area 62 on monitor 48 and clicking.

5 If so, computer 40 advances to block 506 of Fig. 17. if not, computer 40 advances to block 154.

From block 154, computer 40 determines whether the robot control area 54 or 106 was selected by moving the cursor and clicking in the Robot Control area 84 on monitor 48 or the Robot Control area 106 on monitor 50. If the Robot Control was selected, computer 40 advances block 536 of Fig. 18. If the Robot Control was not selected, computer 40 advances to block 158 to determine whether the "Q" key was pressed indicating the operator desires to quit the main program. If the "Q" button was pressed, then computer 40 frees all allocated memory as illustrated at block 160 and ends the main program as illustrated at block 162. If the "Q" button was not pressed at block 158, computer 40 advances back to block 122, waiting for a 20 another button or key to be pressed.

The various functions performed by the system of the present invention will be described in detail. If the Acquire A/P Image button 94 or the F1 key is pressed the, computer 40 advances to block 166 of Fig. 4. Computer 40 then determines whether the image acquisition card is in a passthrough mode at block 168. Button 94 and the F1 key are toggle buttons. When the button 94 or the F1 key is initially pressed, the card is in passthrough mode and images from the C-arm 12 are transmitted directly to the monitor 50. Whatever image is being taken by the C-arm is seen on the monitor 50 in the A/P image area 86. Therefore, if the card is not in the pass-through mode at block 168, pressing button 94 or the F1 key sets the pass-through mode at block 170. Computer 40 then returns 30 to wait for the next command as illustrated at block 172.

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When the button 94 or the F1 key is pressed again after the image acquisition card within the computer 40 is in pass-through mode, it freezes the live image and captures the A/P image as illustrated at block 174. This captured 5 image is then displayed on monitor 50 as illustrated at block 176. Computer 40 then disables and dims buttons F11, F12 and F5, and enables and brightens button 96 and key F3 as illustrated at block 178. In other words, after the A/P image has been captured, computer 40 allows the operator to 10 have the option to select the A/P fiducials through button 96 or key F3.

Computer 40 then assigns a NULL tool as illustrated at block 180. The NULL tool of the robot is the three-dimensional location of end flange 22 of robot 15 18. In other words, the end flange 22 establishes a three-dimensional position for the robot, without depending on the particular surgical instrumentation which may be attached to the end flange 22. Computer 40 determines whether the NULL tool was properly assigned at block 182. 20 If not, computer 40 generates an error message "Tool Not Assigned!" as illustrated at block 184. Computer 40 then waits for the next command as illustrated at block 186. If the NULL tool is assigned properly at block 182, computer 40 gets the current position of the end flange from the 25 robot controller 53 as illustrated at block 188. Computer 40 then determines whether the sagittal image is displayed on monitor 48 as illustrated at block 190. If not, computer 40 sends a message of "Acquire Sagittal Image" as illustrated at block 192, and then returns to wait for the 30 next command at block 194. If the sagittal image is displayed at block 190, computer 40 sends the message "Select the Fiducials" as illustrated at block 196. Computer 40 then returns to wait for the next command at block 198.

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If the Acquire Sagittal Image button 72 or the F2 key is pressed, computer 40 advances to block 200 of Fig.

5. Computer 40 then determines whether the image acquisition card is in a pass-through mode at block 202.

5 Button 72 and the F2 key are toggle buttons. If the card is not in the pass-through mode at block 202, pressing button 72 or the F2 key sets the pass-through mode at block 204. Computer 40 then returns to wait for the next command as illustrated at block 206. When the button 72 or the F2
10 key is pressed again after the image acquisition card within the computer 40 is in pass-through mode, it freezes the live image and captures the sagittal image as illustrated at block 208. This captured image is then displayed on monitor 48 as illustrated at block 210.

15 Computer 40 then disables and dims buttons F11, F12 and F6, and enables and brightens button 74 and key F3 as illustrated at block 212. In other words, after the sagittal image has been captured, computer 40 allows the operator to have the option to select the sagittal
20 fiducials through button 74 or key F4.

Computer 40 then assigns a NULL tool as illustrated at block 214. Computer 40 determines whether the NULL tool was properly assigned at block 216. If not, computer 40 generates an error message "Tool Not Assigned!"
25 as illustrated at block 218. Computer 40 then waits for the next command as illustrated at block 220. If the NULL tool is assigned properly at block 216, computer 40 gets the current position of the end flange 22 from the robot controller 53 as illustrated at block 222. Computer 40
30 then determines whether the A/P image is displayed on monitor 50 as illustrated at block 224. If not, computer 40 sends a message of "Acquire A/P Image" as illustrated at block 226, and then returns to wait for the next command at block 228. If the A/P image is displayed at block 224,
35 computer 40 sends the message "Select the Fiducials" as

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illustrated at block 230. Computer 40 then returns to wait for the next command at block 232.

If the Select A/P Fiducials button 96 or the F3 key button is pressed, computer 40 advances to block 234 of Fig. 6. Computer 40 first determines whether the A/P image is displayed on monitor 50 as illustrated at block 236. If not, computer 40 generates an error message, "Acquire A/P Image" as illustrated at block 238. Computer 40 then returns to wait for the next command as illustrated at block 240.

If the A/P image is displayed at block 236, computer 40 displays a square cursor on the display screen of monitor 50 as illustrated at block 242. Computer 40 then resets the number of located fiducials to zero as illustrated at block 244. Next, computer 40 waits for the trackball button to be clicked by the operator as illustrated as block 246. Once the trackball button is clicked over a fiducial shadow, computer 40 generates a beep as illustrated at block 248. Computer 40 then performs edge detection around the selected mouse cursor coordinate as illustrated at block 250. Such edge detection is performed using a gradient base method developed by John Canny and described in the article referenced in Section [1] of the attached Appendix. Such article is hereby incorporated by reference and made a part of this detailed description.

Computer 40 then determines whether at least 3 edge pixels were found during the edge detection step as illustrated at block 252. If not, computer 40 generates an error message of "Try Again Closer to the Fiducial" as illustrated at block 254. Computer 40 then returns to block 246 to wait for the mouse button to be clicked again. If at least three edge pixels were found at block 252, computer 40 maps the edge pixels to their calibrated image

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coordinates using equation [13] from the attached Appendix as illustrated at block 256.

Computer 40 then finds the center of the fiducial shadow generated by the fiducials 26 using the calibrated 5 edge pixels as set forth in equation [14] of the Appendix. This step is illustrated at block 258. Computer 40 then advances to block 262 of Fig. 6. From block 262, computer 40 draws a circle around the center of the fiducial shadow.

Computer 40 then determines whether all eight of 10 the fiducials 26 have been located in the A/P image as illustrated at block 264. If not, computer 40 returns to block 246 of Fig. 6 and then waits for the mouse button to be clicked again over a different fiducial shadow.

If all eight fiducials have been located at block 15 264, computer 40 then saves the established image coordinates of all the fiducials in the computer memory as illustrated at block 268. Computer 40 then enables and brightens the Register A/P Image Button 98 and F5 key as illustrated at block 270. Computer 40 then transmits the 20 message "Register A/P Image" as illustrated at block 272.

Next, computer 40 automatically advances to location ENTRY1 of Fig. 8 as illustrated at Block 274. Computer 40 does not wait for an operator to press a button to move to location ENTRY1 of Fig. 8.

25 If the Select Sagittal Fiducials or the F4 key button is pressed, computer 40 advances to block 276 of Fig. 7. Computer 40 first determines whether the sagittal image is displayed on monitor 48 as illustrated at block 278. If not, computer 40 generates an error message, 30 "Acquire Sagittal Image" as illustrated at block 280. Computer 40 then returns to wait for the next command as illustrated at block 282.

If the sagittal image is displayed at block 278, computer 40 displays a square cursor on the display screen 35 of monitor 48 as illustrated at block 290. Computer 40

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then resets the number of located fiducials to zero as illustrated at block 292. Next, computer 40 waits for the trackball button to be clicked by the operator as illustrated as block 294. Once the trackball button is 5 clicked, computer 40 generates a beep as illustrated at block 296. Computer 40 then performs edge detection around the selected trackball cursor coordinate as illustrated at block 298. Such edge detection is performed using a gradient base method developed by John Canny and described 10 in the article referenced in Section [1] of the attached Appendix.

Computer 40 then determines whether at least 3 edge pixels were found during the edge detection step as illustrated at block 300. If not, computer 40 generates an 15 error message of "Try Again Closer to the Fiducial" as illustrated at block 302. Computer 40 then returns to block 294 to wait for the trackball button to be clicked again. If at least three edge pixels were found at block 300, computer 40 maps the edge pixels to their calibrated 20 image coordinates using equation [13] from the attached Appendix as illustrated at block 304.

Computer 40 then finds the center of the fiducial shadow generated by the fiducials 26 using the calibrated edge pixels as set forth in equation [14] of the Appendix. 25 This step is illustrated at block 306. Computer 40 then advances to block 310. From block 310, computer 40 draws a circle around the center of the fiducial shadow. Computer 40 then determines whether all eight of the fiducials 26 have been located in the sagittal image as illustrated at 30 block 312. If not, computer 40 returns to block 294 and then waits for the trackball button to be clicked again.

If all eight fiducials have been located at block 312, computer 40 then saves the established image coordinates of all the fiducials in the computer memory as 35 illustrated at block 316. Computer 40 then enables and

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brightens the Register sagittal Image Button 76 and the F6 key as illustrated at block 318. Computer 40 then transmits a message of "Register Sagittal Image" as illustrated at block 320.

5 Next, computer 40 automatically advances to location ENTRY2 of Fig. 9 as illustrated at block 322. Computer 40 does not wait for an operator to press a button to move to location ENTRY2 of Fig. 9.

10 If the Register A/P Image button 98 or the F5 key was pressed, computer 40 advances to block 324 of Fig. 8. Computer 40 first determines whether all of the A/P fiducials have been found as illustrated at block 326. If not, computer 40 generates an error message of "Haven't Selected All the Fiducials" as illustrated at block 328. 15 Computer 40 then returns to wait for the next command as illustrated at block 330.

If all the A/P fiducials have been found at block 326, computer 40 advances to block 332. As discussed above, computer 40 also automatically advances to block 332 from block 274 of Fig. 6 after all the fiducials have been selected.

In block 332, computer 40 first recalls all the two-dimensional coordinates of the A/P fiducial centers. Next, the computer 40 reads in data from a file of the 25 three-dimensional coordinates of the center of the fiducials 26 as illustrated at block 334. The three-dimensional coordinates of the fiducials 26 are obtained using a Coordinate Measurement Machine (CMM). Therefore, this data provides information related to the 30 actual location of the fiducials 26. Typically, these CMMed coordinates are obtained from the manufacturer of the registration artifact 24.

Next, computer 40 optimizes the parameters of a geometric model which projects three dimensional 35 coordinates into corresponding image points. The optimized

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model is encapsulated in a registration matrix as set forth in section [3]. Optimization is performed by minimizing (in a least squares sense) the deviation between the model's projections of the three-dimensional coordinates read at
5 block 334, and the two-dimensional coordinates read at block 332. The Levenberg-Marquardt method is used for optimization, as described in equation [2] of the attached Appendix and as illustrated at block 336. Computer 40 then constructs a registration matrix as set forth in
10 section [3] of the attached Appendix. This step is illustrated at block 338.

Computer 40 next determines whether the sagittal image has been registered as illustrated at block 340. If not, computer 40 generates a message of "Perform Sagittal
15 Registration" as illustrated at block 342. Computer 40 then returns to wait for the next command as illustrated at block 344.

If the sagittal image has been registered at block 340, computer 40 generates a display message of "Pick
20 Entry Point" as illustrated at block 346. Computer 40 then returns to wait for the next command as illustrated at block 348.

If the Register sagittal Image button 76 or the F6 key have been pressed, computer 40 advances to block 350
25 of Fig. 9. Computer 40 first determines whether all of the sagittal fiducials have been found as illustrated at block 352. If not, computer 40 generates an error message of "Haven't Selected All the Fiducials" as illustrated at block 354. Computer 40 then returns to wait for the next
30 command as illustrated at block 356.

If all the sagittal fiducials have been found at block 352, computer 40 advances to block 358. As discussed above, computer 40 also automatically advances to block 358 from block 322 of Fig. 7 after all the fiducials have been
35 selected.

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In block 358, computer 40 first recalls all the two-dimensional coordinates of the sagittal fiducial centers. Next, the computer 40 reads in data from a file of the three-dimensional coordinates of the center of the 5 fiducials 26 as illustrated at block 360. The coordinates of the fiducials 26 are obtained using a Coordinate Measurement Machine (CMM). Therefore, this data provides information related to the actual location of the fiducials 26. Typically, these coordinates are obtained from the 10 manufacturer of the registration artifact 24.

Next, computer 40 optimizes the fit between the three-dimensional coordinates read at block 360 and the two-dimensional coordinates read at block 358 using the Levenberg-Marquardt method described in equation [2] of the 15 attached Appendix as illustrated at block 362. Computer 40 then constructs a registration matrix as set forth in section [4] of the attached Appendix. This step is illustrated at block 364.

Computer 40 next determines whether the A/P image 20 has been registered as illustrated at block 366. If not, computer 40 generates a message of "Perform A/P Registration" as illustrated at block 368. Computer 40 then returns to wait for the next command as illustrated at block 370.

25 If the A/P image has been registered at block 366, computer 40 generates a message of "Pick Entry Point" as illustrated at block 372. Computer 40 then returns to wait for the next command as illustrated at block 374.

If the transverse angle button 100 or the F7 key 30 is pressed, computer 40 advances to block 376 of Fig. 10. The transverse angle is the angle determined by using the right hand rule about the X axis 34 of Fig. 1. To adjust the transverse angle, the operator places the cursor in the Entry Field button 101 of Fig. 3a as illustrated at block 35 378 of Fig. 10. The operator then enters a numeric value

-28-

for the transverse angle as illustrated at block 380. Computer 40 then reads the new transverse angle, and updates the orientation of the virtual guidewire using the equations set forth in section [6] of the attached
5 Appendix. This step is illustrated at block 382. Next, computer 40 redraws the virtual guidewire projection 92 in the A/P image area 86 and 68 in the sagittal image area 62 based on the new transverse angle using the equation set forth in section [7] of the attached Appendix as
10 illustrated at block 384. Computer 40 then returns to wait for the next command as illustrated at block 386.

If the Screw Length button 80 or the F8 key was pressed, computer 40 advances to block 388 of Fig. 11. The cursor is then placed on the entry field 81 of Fig. 3b as
15 illustrated at block 390. The operator then enters the numeric value for the new screw length as illustrated at block 392. Computer 40 reads the new screw length, and updates the length of the virtual guidewire using the equations set forth in section [11] of the Appendix. This
20 step is illustrated at block 394. Next, computer 40 redraws the projected guidewire 92 in the A/P image area 86 and the projected guidewire 68 in the sagittal image area 62 using the equations set forth in section [7] of the Appendix. These steps are illustrated at block 396. Next,
25 computer 40 returns to wait for the next command as illustrated at block 398.

If the Sagittal Angle button 78 or the F10 key is pressed, computer 40 advances to block 400 of Fig. 13 to adjust the sagittal angle. The sagittal angle is the angle
30 about the Y-axis 36 of Fig. 1 using the right hand rule.

The cursor is placed in an entry field 79 of Fig. 3b as illustrated at block 402. Next, the operator enters a numeric value for the sagittal angle as illustrated at block 404. Computer 40 then reads the value of the new
35 sagittal angle, and updates the orientation of the virtual

-29-

guidewire using the equations set forth in section [10] of the Appendix. These steps are illustrated at block 406. Next, computer 40 redraws the projected guidewire 92 in the A/P image area 86 and the projected guidewire 68 in the 5 sagittal image area 62 using the equations set forth in section [7] of the Appendix. These steps are illustrated at block 408. The computer 40 then returns to wait for the next instruction as illustrated at block 410.

If the Approach Angle button 102 or the F9 key 10 was pressed, computer 40 advances to block 412 of Fig. 12. The approach angle is the angle taken about the Z-axis 38 of Fig. 1 using the right hand rule.

The cursor is placed in the entry field 103 of Fig. 3a as illustrated at block 414. The operator then 15 enters a numeric value for the new approach angle as illustrated at block 416. The computer 40 then reads the new approach angle as illustrated at block 418. Computer 40 then returns to wait for the next command as illustrated at block 420.

In order to plan a linear trajectory in space, 20 only two angles are needed, for this particular procedure the transverse angle and the sagittal angle are used. The approach angle permits the surgeon to control movement of the robot. In other words, the approach angle is not used 25 with the planning of the trajectory.

If the Move Robot button 104, or the F11 key are 30 pressed, computer 40 advances to block 422 of Fig. 14. Computer 40 first recalls the approach angle from memory as illustrated at block 424. Next, computer 40 recalls the sagittal angle, the transverse angle and the three-dimensional coordinates of the top point of the virtual guidewire as illustrated at block 426. Next, computer 40 calculates the planned position and orientation 35 using the equations in section [12] of the Appendix. This step is set forth at block 428. Next, computer 40 reads in

-30-

data from a file related to the specific surgical end-effector being used for the surgical procedure as illustrated at block 430. This data includes the three-dimensional coordinates from the Coordinate

5 Measurement Machine (CMM).

Computer 40 determines whether the surgical end-effector is properly assigned at block 434. If not, computer 40 generates an error message of "Surgical end-effector Not Assigned" as illustrated at block 436.

10 Computer 40 then returns to wait for the next command as illustrated at block 438.

If the surgical end-effector is properly assigned at block 434, computer sends a command through serial communication port 50 to the robot controller 53 to move 15 the robot to the planned position and orientation as illustrated at block 440. Computer 40 assigns the "NULL" end-effector as illustrated at block 442. Computer 40 determines whether the NULL end-effector was properly assigned at block 444. If not, computer 40 generates an 20 error message of "NULL end-effector Not Assigned" as illustrated at block 446. Computer 40 then returns to wait for the next command at block 448. If the NULL end-effector is properly assigned at block 444, computer 40 returns to wait for the next command as illustrated at 25 block 450.

If the Move Robot Along Axis button 82 of Fig. 3b is selected, computer 40 advances to block 452 of Fig. 15. The computer 40 has already moved the robot to the proper orientation during the steps of Fig. 20. Therefore, the 30 steps of Fig. 21 are designed to move the robot along the tool guide axis defined by the tool guide 28 of Fig. 2. The tool guide axis typically moves toward and away from the body on the table 14 along the tool guide axis. Computer 40 determines whether a thread entitled "Move 35 Robot Axis" has been dispatched at block 454. This thread

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program runs by itself until it is stopped. If the program is not started at block 454, computer 40 starts this program as illustrated at block 456. Computer 40 then returns to wait for additional instructions at block 458.

- 5 If the thread program has started at block 454, then computer determines whether the Page Up button has been pressed at block 460. If not, computer 40 determines whether the Page Down button has been pressed at block 462. If not, computer 40 returns to block 464 to wait for the
- 10 next command.

If the Page Up button was pressed at block 460, computer 40 determines whether the Page Up button is still being pressed at block 466. If not, computer 40 returns to wait for the next command as illustrated at block 468. If
15 the Page Up button is still being pressed at block 466, computer 40 sends a VAL command from communication port 50 to robot controller 53 to move the robot in the positive tool guide axis direction as illustrated at block 470. The positive tool guide axis direction is up away from the
20 patient. Computer 40 then returns to block 466.

If the Page Down button has been pressed at block 462, computer 40 determines whether the Page Down button is still being pressed at block 472. If not, computer 40 returns at block 468 to wait for the next command. If the
25 Page Down button is still being pressed at block 472, computer 40 sends a VAL command to move the robot in the negative tool guide axis direction as illustrated at block 474. The negative tool guide axis direction is down toward the patient. Computer 40 then returns to block 472.

30 In other words, the control steps of Fig. 15 permit the operator to move the robot along its tool guide axis. Once the robot is moving in either the positive or negative direction, it keeps moving until the Page Up or Page Down are released. The entire robot moves in order to
35 maintain the end-effector 24 and the tool guide 28 in the

-32-

same orientation along the planned axis. In other words, the end-effector 24 of robot 18 may be maintained in an orientation that is 45° relative to Z-axis 38 of Fig. 1. VAL is the program control language for the PUMA-560 controller 53. It is understood that other robots, controllers, and program languages may be used in accordance with the present invention.

If a cursor is over the A/P image area 86 of Fig. 3a, computer 40 advances to block 476 of Fig. 16. Computer 10 40 waits for the trackball to be clicked in the A/P image area 86 as illustrated at block 478. Once the trackball has been clicked at block 478, computer 40 determines whether both the A/P image and the sagittal image have been registered as illustrated at block 480. If not, computer 15 40 does nothing and returns to block 482 to wait for the next command.

If the A/P and the sagittal images have been registered at block 480, computer 40 determines whether the projected guidewire is drawn as illustrated at block 484. 20 If not, computer 40 assumes that the operator intends to draw the projected guidewire. Therefore, the computer 40 draws a cross hair at trackball coordinate (U,V) as illustrated at block 486. Next, computer 40 draws a curve representing the line of site on the sagittal image using 25 the equations of section [5] of the attached Appendix as illustrated at block 488. A curve is drawn representing the line of site due to the distortion in the images. If you take an x-ray of a straight line, its image will be a curve due to the distortions inherent in the fluoroscope's 30 image intensifier. This is why a curve must be drawn to represent the line of sight. Once the line of sight indicator 70 is drawn on the sagittal image area 62 of Fig. 3b, computer 40 returns to wait for the next command as illustrated at block 490.

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If the projected guidewire is already drawn at block 484, computer 40 determines whether the trackball coordinates are within five pixels from the top point 88 in the A/P image area 86. This step is illustrated at block 5 492. If the cursor coordinates are within five pixels from the top point 88, computer 40 erases the projected guidewire as illustrated at block 494 and returns to wait for the next command as illustrated at block 496.

If the trackball cursor coordinates are not 10 within five pixels from the top point 88 at block 492, computer 40 determines whether the trackball coordinates are within five pixels of the bottom point 90 as illustrated at block 498. If not, computer 40 returns to wait for the next command as illustrated at block 490. If 15 the trackball cursor coordinates are within five pixels from the bottom point 90 at block 498, computer 40 determines whether the trackball has been clicked again as illustrated at block 500. If so, computer 40 returns to block 490 to wait for the next command. If not, computer 20 40 updates the transverse or sagittal angle as illustrated at block 502 based on movement of the trackball. The transverse angle value is incremented if the trackball is being moved up. The transverse angle value is decreased if the trackball is moving down. The sagittal angle value is 25 incremented if the trackball is being moved right. The sagittal angle value is decreased if the trackball is moving left. The incrementing factor is 0.1° per pixel. The equations for this step are set forth in section [6] of the Appendix.

30 After the transverse and/or sagittal angle have been updated at block 502, computer 40 redraws the projected guidewire 92 in the A/P image area 86 and the projected guidewire 68 in the sagittal image area 62 using the equations in section [7] of the attached Appendix.

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These steps are illustrated at block 504. Computer 40 then returns to block 500.

If the cursor is over the sagittal image area 62 of Fig. 3b, computer 40 advances to block 506 of Fig. 17.

5 Computer 40 determines whether the line of sight has been drawn at block 508. If not, computer 40 returns to wait for the next command at block 510. If the line of sight has been drawn at block 508, computer 40 draws the projected guidewire 92 in the A/P image area 86 and the projected guidewire 68 in the sagittal image area 62 using the equations in section [8] of the Appendix. These steps are illustrated at block 512. Computer 40 also checks if the robot has been initialized at block 513, if it has then computer 40 enables and brightens buttons "Move Robot" 104, and "Move Along Drill Axis" 82, and keys F11, and F12 at block 513.5. Next, computer 40 waits for the track ball in the sagittal image area 62 to be clicked as illustrated at block 514. If robot has not been initialized then computer 40 waits for the track ball in the sagittal image area 62 to be clicked as illustrated at block 514. Next, computer 40 determines whether the trackball cursor coordinates are within five pixels from the top point 64 as illustrated at block 516. If not, computer 40 determines whether the trackball coordinates are within five pixels of the bottom point 66 as illustrated at block 518. If not, computer 40 returns at block 520 to wait for the next command.

If the trackball coordinates are within five pixels of the top point 64 at block 516, computer 40 determines whether the trackball has been clicked again at block 522. If so, computer 40 returns at block 524 to wait for the next command. If not, computer 40 updates the position of the virtual guidewire 68 by moving it along the line of sight in the same direction as the trackball movements. The incrementing ratio is 0.1° mm/pixel. This step is illustrated at block 526. The computer uses the

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equations set forth in section [9] of the Appendix to update the virtual guidewire position. Computer 40 then redraws the projected guidewire 68 in the sagittal image area 62 and also redraws the projected guidewire 92 in the A/P image area 86 as illustrated at block 528 by using the equations set forth in Section [7] of the Appendix. Computer 40 then returns back to block 522.

If the trackball coordinates are within five pixels from the bottom point 66 at block 518, computer 40 determines whether the trackball has been clicked again at block 530. If so, computer 40 returns at block 524 to wait for the next command. If not, computer 40 assumes that the operator wants to adjust the position of bottom point 66. Therefore, computer 40 updates the sagittal and/or transverse angle as illustrated at block 532 based on movement of the trackball. The transverse angle value is incremented if the trackball is being moved up. The transverse angle value is decreased if the trackball is moving down. The sagittal angle value is incremented if the trackball is being moved to the right. The sagittal angle value is decreased if the trackball is moving to the left. The incrementing ratio is 0.1° /pixel. Computer 40 uses the equations of section [10] of the Appendix for these steps as illustrated at block 532. Next computer 40 redraws the projected guidewire 68 in the sagittal image area 62 and the projected guidewire 92 in the A/P image area 86 as illustrated at block 534 using the equations set forth in Section [7] of the Appendix. Computer 40 then returns to block 530.

If the Robot Control areas 84 of Fig. 3a-b is selected, computer 40 advances to block 536 of Fig. 18. Computer 40 then displays a menu giving the user options at block 538. The first option is a "Initialize Robot" option. Computer 40 determines whether the Initialize Robot menu item was selected at block 540. If so, computer

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40 opens the serial communication port 52 for communication with the robot controller 53 as illustrated at block 542.

Computer 40 sends the VAL program language commands required to initialize the robot controller 53 as

5 illustrated at block 544. Computer 40 determines whether VAL was initialized properly at block 546. If VAL was not initialized properly then the computer 40 sends message VAL not initialized 53 as illustrated at block 548. Computer 40 then returns at block 550.

10 If VAL was properly initialized at block 546, computer 40 transmits preestablished HOME and START positions to the robot controller 53 as illustrated at block 552. The HOME and START position are two positions in the work space of the robot. In addition, computer 40
15 initializes the preestablished NULL end-effector and SURGICAL end-effector as illustrated at block 554. In other words, computer 40 sends specifications to the precise configurations of the specific surgical instrument that is going to be used. Therefore, the controller 53 is
20 programmed to move the robot to these positions. During *operation, computer 40 can instruct the controller 53 to move to the particular HOME or START positions. In addition, controller 53 will recognize instructions for the particular surgical end-effector which was initialized
25 during step 554. Next, the robot speed is set to a very slow speed as illustrated at block 556. For example, the robot speed is set to a speed of 5 out of 256. Next, the computer 40 checks if the virtual guidewire has been planned, if it has then it enables and brightens buttons
30 "Move Robot" 104 and "Move Robot Along Tool Axis" 82 and keys F11, F12, as illustrated in block 557.5. Computer 40 then returns to wait for the next instruction as illustrated at block 559.

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If the virtual guidewire has not been planned, computer 40 then returns to wait for the next instruction as illustrated at block 558.

If an option entitled "Move to a Predefined Location" was selected from the pop-up menu 538 and if the robot was already initialized as illustrated at block 560, then computer 40 displays a dialog box with options to move the robot to the predefined locations as illustrated at block 562. In other words, a dialog box with the options to move the robot to the HOME position or the START position are displayed. The operator can select one of these options at block 562. Computer 40 then sends a VAL command to controller 53 to move the robot 18 to the specified location as illustrated at block 564. Computer 40 then returns at block 568 to wait for the next command.

If computer 40 determines that the option "Assigned Predefined Tool" was selected from the menu 538 and if the robot has already been initialized as illustrated at block 570, then computer 40 displays a dialog box with options to assign the predefined tools established during the initialization step at block 554. This step is illustrated at block 574. In other words, computer 40 displays a dialog box for assigning either the NULL end-effector or the SURGICAL end-effector at block 574. Once the desired tool is selected, computer 40 transmits to VAL the command to assign the specified end-effector to controller 53 as illustrated at block 576. Computer 40 then returns to wait for the next command at block 578. If the assigned predefined end-effector item was not selected or the robot was not initialized at block 570, computer 40 returns at block 572 to wait for the next command.

Although the invention has been described in detail with reference to a certain preferred embodiment, variations and modifications exist within the scope and

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spirit of the present invention as described and defined in
the following claims.

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WHAT IS CLAIMED IS:

1. A method for planning a stereotactic surgical procedure using a fluoroscope for generating images of the body, the method comprising the steps of:

 placing adjacent to the body a registration artifact including a plurality of fiducials at known positions relative to a known coordinate frame of the artifact;

 displaying on a computer monitor an image taken of the patient's body and the registration artifact;

 receiving an input to identify two-dimensional coordinates of the fiducials of the registration artifact displayed on the image; and

 registering the image by creating a geometric model having parameters, said model projecting three-dimensional coordinates into image points, and numerically optimizing the parameters of the geometric model such that the projections of the known three-dimensional coordinates of the fiducials best fit the identified two-dimensional coordinates in the image.

2. The method of claim 1, further comprising the steps of:

 displaying a second image taken of the patient's body and the registration artifact but from an angle different from that of the first image;

 receiving an input to identify two-dimensional coordinates of the fiducials of the registration artifact displayed on the second image; and

 registering the second image by creating a geometric model having parameters, said model projecting three-dimensional coordinates into image points, and numerically optimizing the parameters of the geometric model such that the projections of the known

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three-dimensional coordinates of the fiducials best fit the identified two-dimensional coordinates in the second image.

3. The method of claim 2, further comprising the step of receiving a user input to select a point upon the first image, said point partially designating a virtual guidewire.

4. The method of claim 3, further comprising the step of receiving an input specifying a position, a length, and angles of the virtual guidewire.

5. The method of claim 4, further comprising the step of drawing projected guidewire segments on the images, such that the projected guidewires are projections of the virtual guidewire onto the images.

6. The method of claim 5, further comprising the steps of receiving a user input to move either end of the projected guidewire on either image, by revising the virtual guidewire of which the two projected guidewires are projections, and by redrawing the two projected guidewires on their respective images in correspondance with the revised virtual guidewire.

7. The method of claim 5, further comprising the steps of receiving a user input to change the length of the virtual guidewire, and redrawing the two projected guidewires on their respective images in correspondance with the revised virtual guidewire.

8. The method of claim 5, further comprising the steps of receiving a user input to change the sagittal angle of the virtual guidewire, updating the orientation of the virtual guidewire based on the new sagittal angle, and redrawing the two projected guidewires on their respective images in correspondance with the revised virtual guidewire.

9. The method of claim 5, further comprising the steps of receiving a user input to adjust the transverse angle of the virtual guidewire, updating the

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orientation of the virtual guidewire based on the new transverse angle, and redrawing the two projected guidewires on their respective images in correspondance with the revised virtual guidewire.

10. The method of claim 5, further comprising the steps of receiving a user input to adjust the coronal angle of the virtual guidewire, updating the orientation of the virtual guidewire based on the new coronal angle, and redrawing the two projected guidewires on their respective images in correspondance with the revised virtual guidewire.

11. The method of claim 5, further comprising the step of producing an output to adjust the coordinates of a tool guide such that its axis is brought into alignment with the virtual guidewire.

12. The method of claim 11, further comprising the step of producing an output to adjust the coordinates of a tool guide such that the position of the guide along its axis is offset by a preselected distance from one endpoint of the virtual guidewire.

13. The method of claim 11, further comprising the step of transmitting said coordinates to an automatic mechanical device.

14. The method of claim 11, further comprising the step of displaying said coordinates with which a human operator may manually adjust a mechanical device.

15. The method of claim 11, wherein the registration artifact includes a tool guide.

16. The method of claim 2, further comprising the step of receiving an input to select a point upon the first image, said point partially designating a virtual targetpoint for a surgical instrument.

17. The method of claim 16, further comprising the step of drawing a projected targetpoint both on the first image and another on the second image, such that the

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projected targetpoints are projections of a virtual targetpoint onto the images.

18. The method of claim 17, further comprising the steps of receiving a user input to move the projected targetpoint on either image, by revising the virtual targetpoint of which the two projected targetpoints are projections, and by redrawing the two projected targetpoints on their respective images in correspondance with the revised virtual targetpoint.

19. The method of claim 18, further comprising the step of producing an output to adjust the coordinates of a tool guide such that its axis intersects the virtual targetpoint.

20. The method of claim 19, further comprising the step of producing an output to adjust the coordinates of a tool guide such that the position of the guide along its axis is offset by a preselected distance from the virtual targetpoint.

21. The method of claim 19, further comprising the step of transmitting said coordinates to an automatic mechanical device.

22. The method of claim 19, further comprising the step of displaying said coordinates with which a human operator may manually adjust a mechanical device.

23. The method of claim 19, wherein the registration artifact includes a tool guide.

24. The method of claim 1, further comprising the step of receiving an input to select a point upon the first image, said point partially designating a virtual guidewire representing a trajectory for the surgical instrument into the body.

25. The method of claim 24, further comprising the step of producing an output to adjust the coordinates of a tool guide such that its axis is brought into alignment with the virtual guidewire.

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26. The method of claim 25, further comprising the step of transmitting said coordinates to an automatic mechanical device.

27. The method of claim 25, further comprising the step of displaying said coordinates with which a human operator may manually adjust a mechanical device.

28. The method of claim 25, wherein the registration artifact includes a tool guide.

29. An apparatus for planning a stereotactic surgical procedure using a fluoroscope for generating images of the body, the apparatus comprising:

means for placing adjacent to the body a registration artifact including a plurality of fiducials;

means for displaying an image taken of the body and the fiducials;

means for identifying two-dimensional coordinates of the fiducials in an image;

means for registering an image with respect to said fiducial artifact;

means for receiving inputs to select and adjust a virtual guidewire or targetpoint, while the projections of said guidewire or targetpoint are displayed superimposed upon the image; and

means for producing an output to adjust the coordinates of a tool guide.

30. An apparatus for planning a stereotactic surgical procedure for a linear trajectory insertion of a surgical instrument into a body using a fluoroscope for generating images of the body, the apparatus comprising:

a registration artifact located adjacent to the body, the registration artifact including a plurality of fiducials located at known three-dimensional coordinates relative a known coordinate frame;

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means for displaying at least one image taken of the body and the fiducials on at least one computer monitor;

means for identifying two-dimensional coordinates of the fiducials in each image; and

means for numerically optimizing parameters of a geometric model, said model projecting three-dimensional coordinates into image points, such that the projections of the known three-dimensional coordinates of the fiducials best fit the identified two-dimensional coordinates in the image.

31. The apparatus of claim 30, further comprising a means for receiving user input to select a position, a length, and the angles of a virtual guidewire; and means for displaying a projected guidewire segment on each registered image representing the location of the virtual guidewire.

32. The apparatus of claim 30, further comprising a tool guide, and means for producing an output to adjust the coordinates of the tool guide.

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ABSTRACT OF THE DISCLOSURE

An apparatus and method is provided for coordinating two fluoroscope images, which permits accurate computer-based planning of the insertion point and angle of approach of a needle, drill, screw, nail, wire or other surgical instrumentation into the body of a patient, and subsequently guides the surgeon in performing the insertion in accordance with the plan.

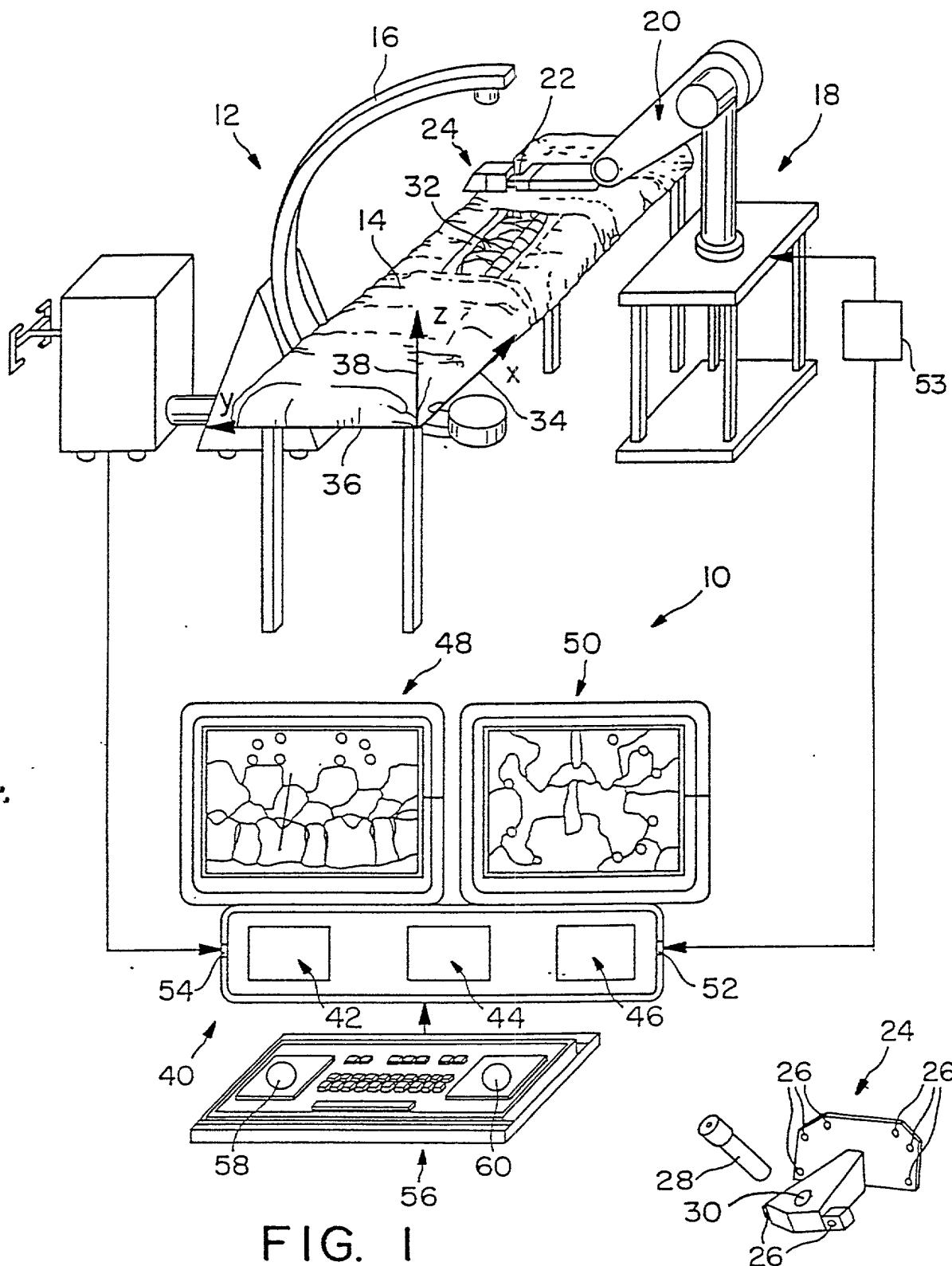


FIG. I

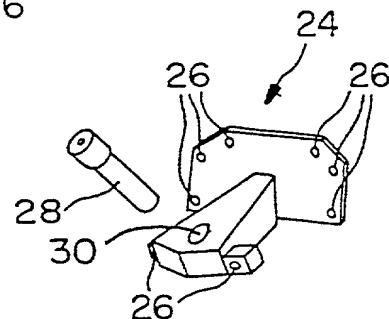


FIG. 2

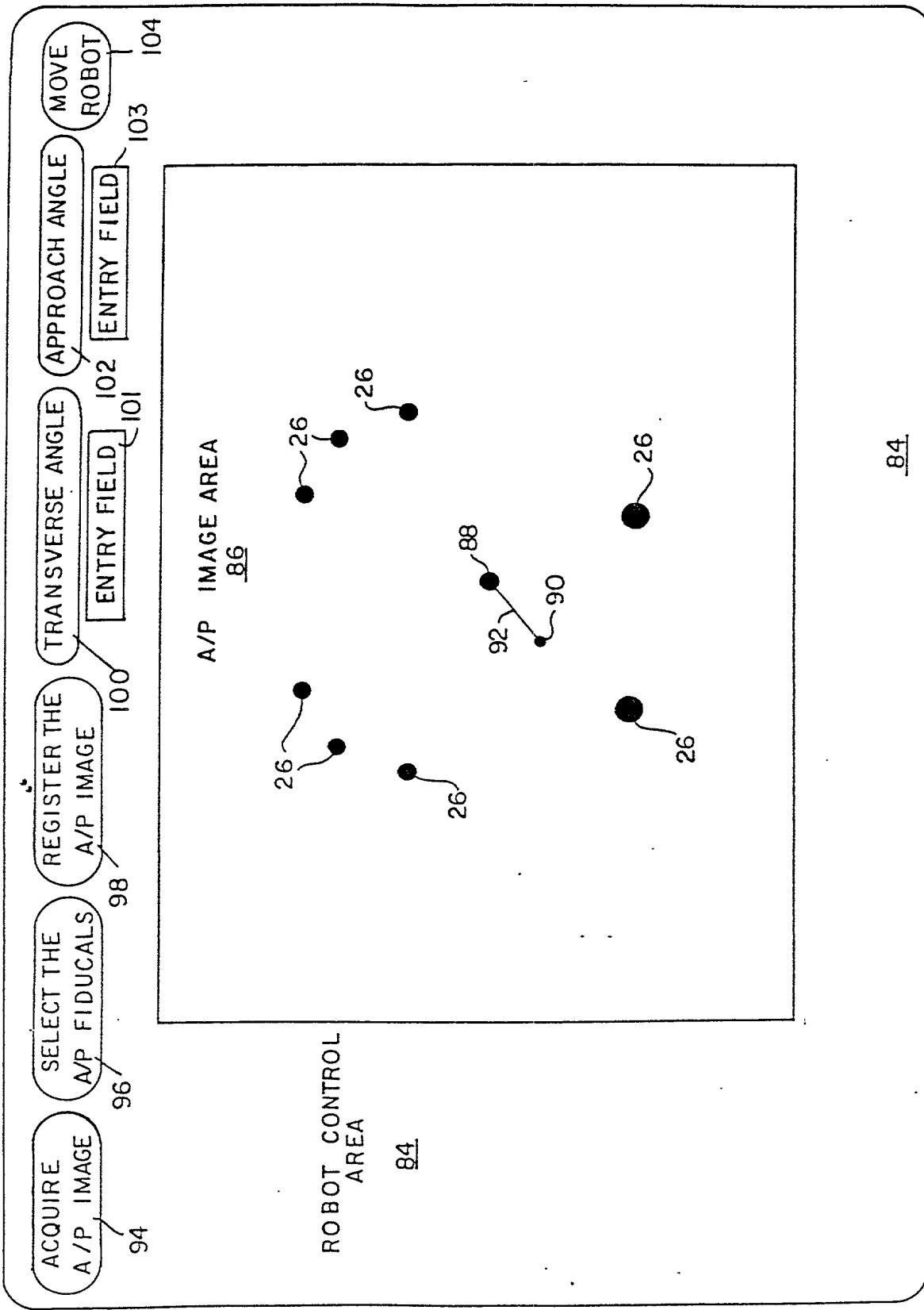


FIG. 3a

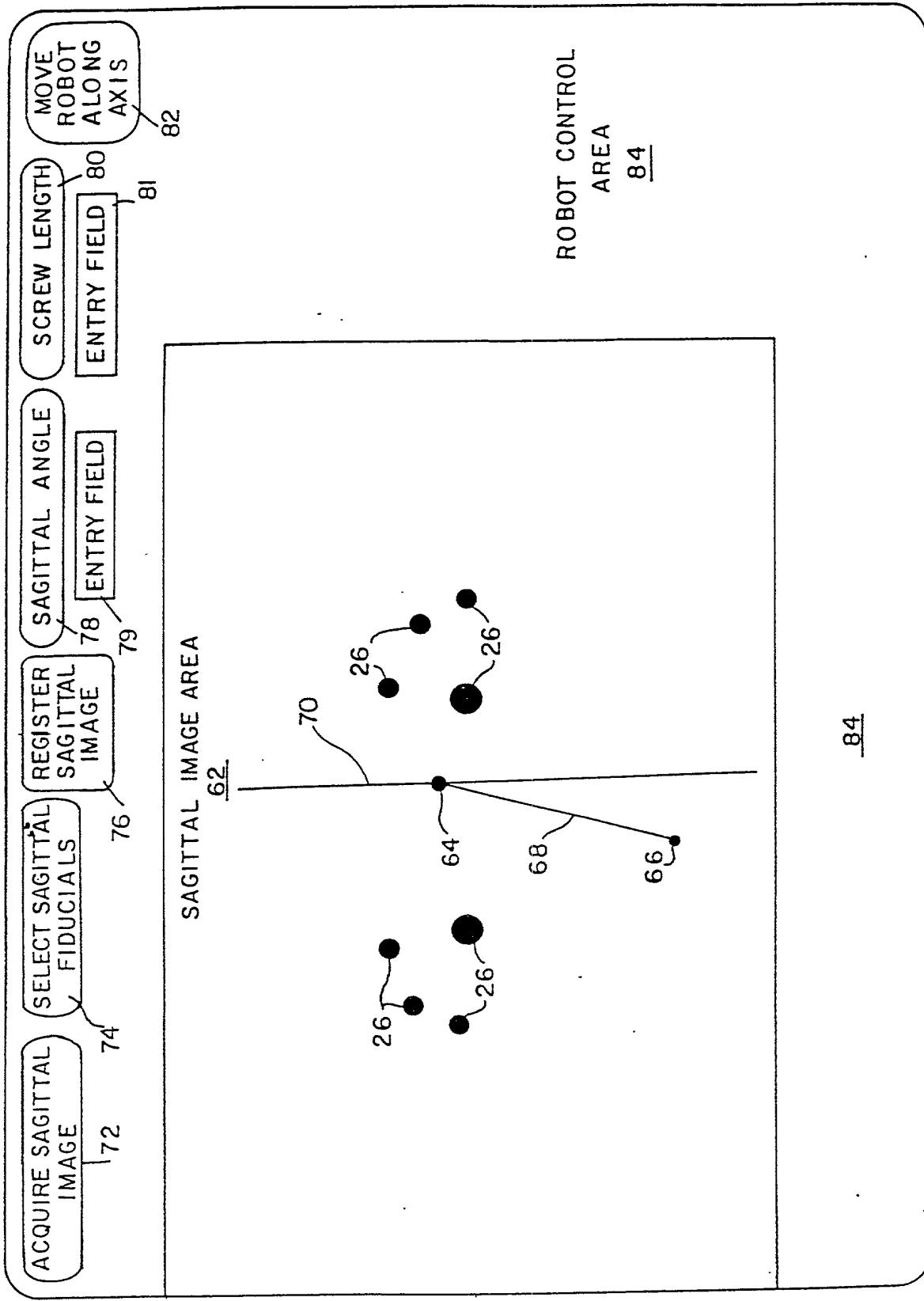
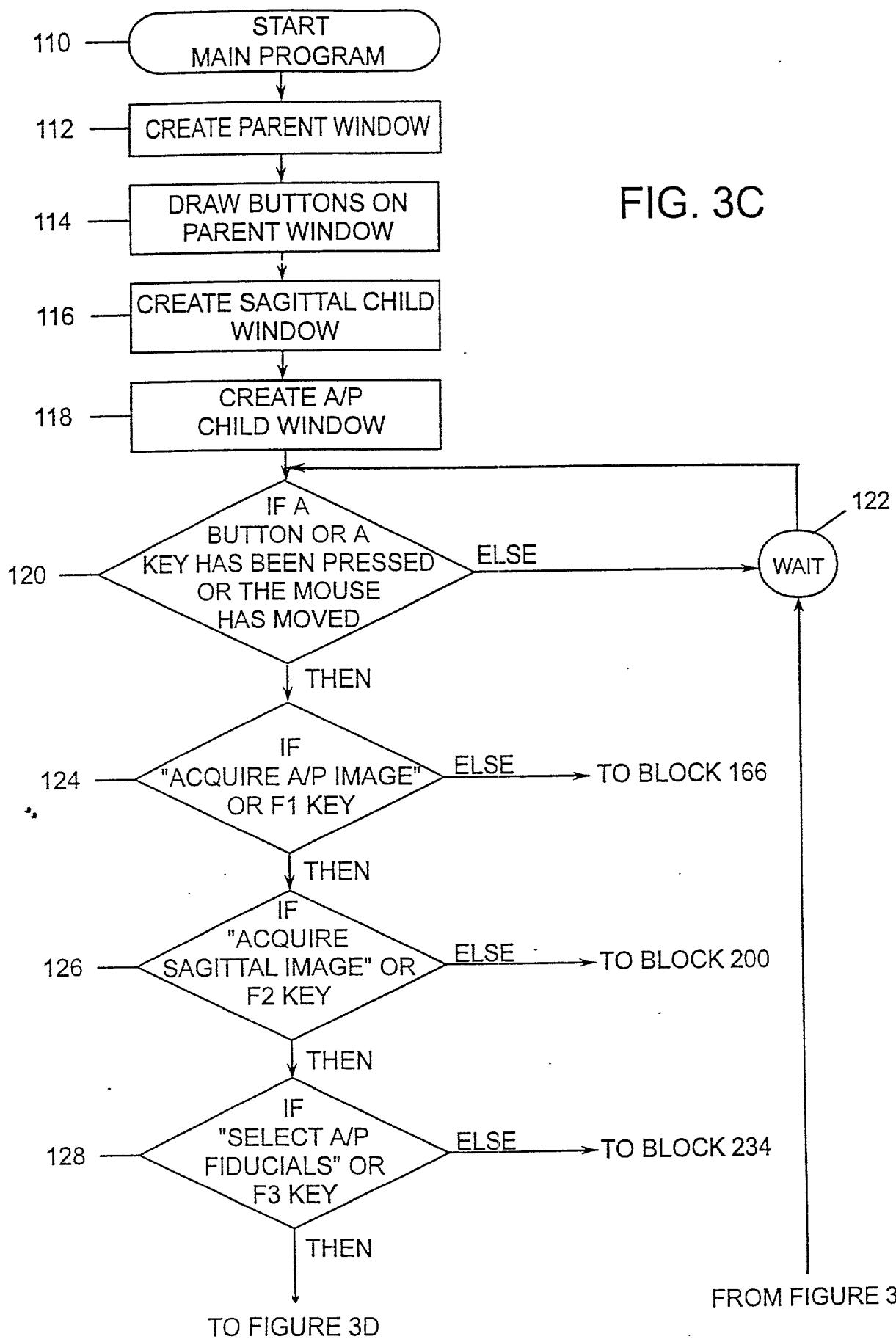


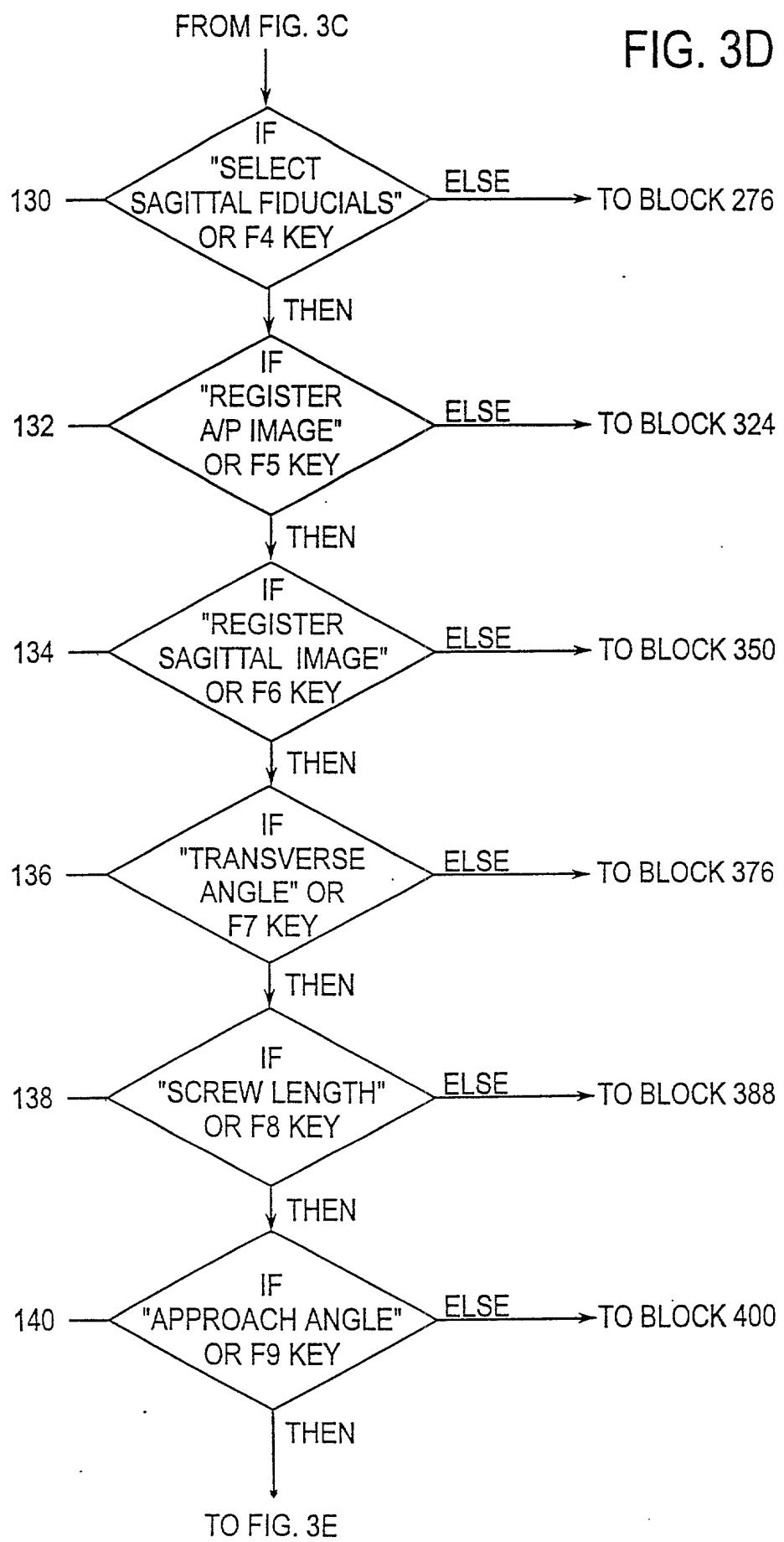
FIG. 3b

FIG. 3C



FROM FIGURE 3F

FIG. 3D



FROM FIG. 3D

FIG. 3E

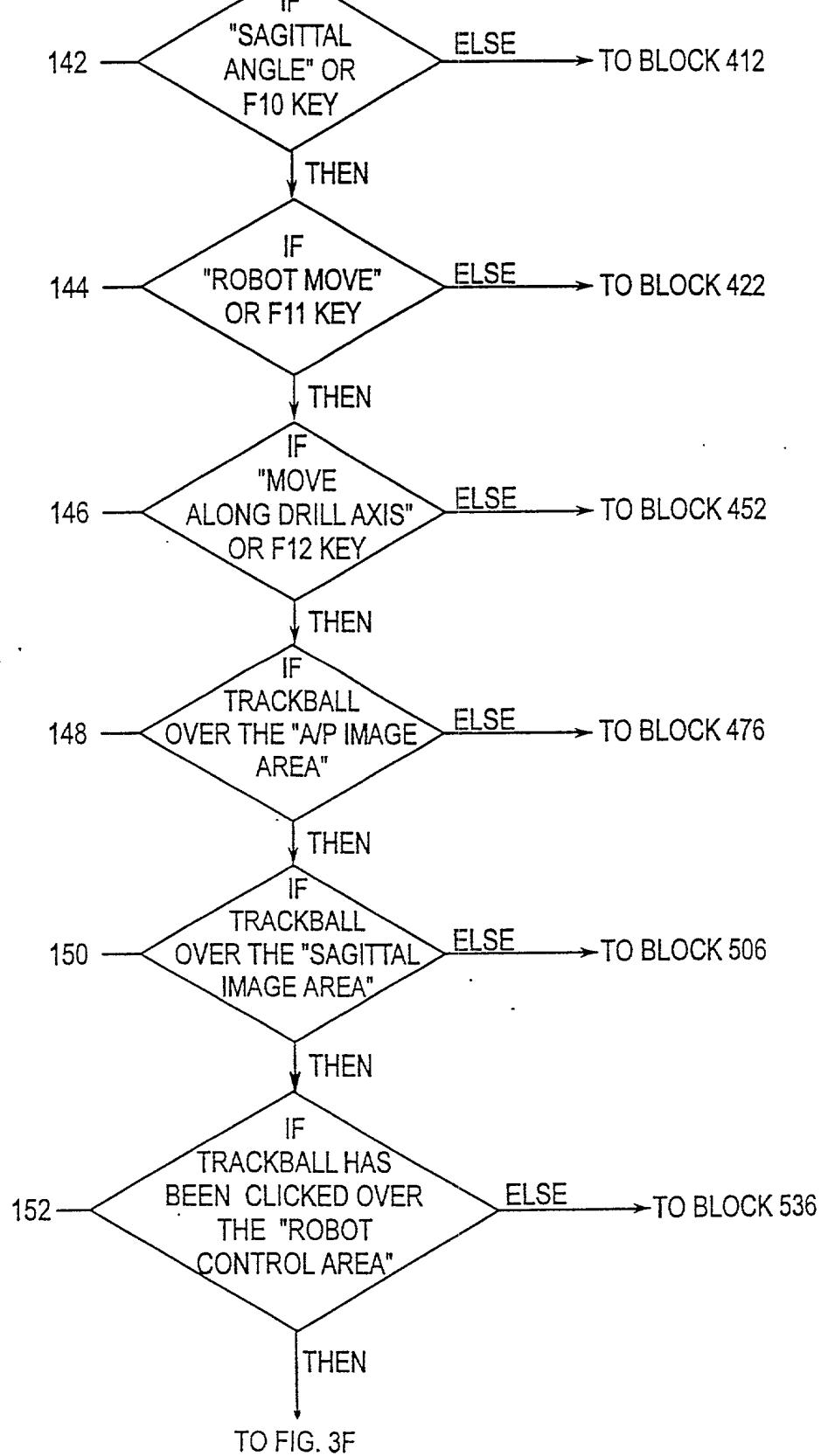


FIG. 3F

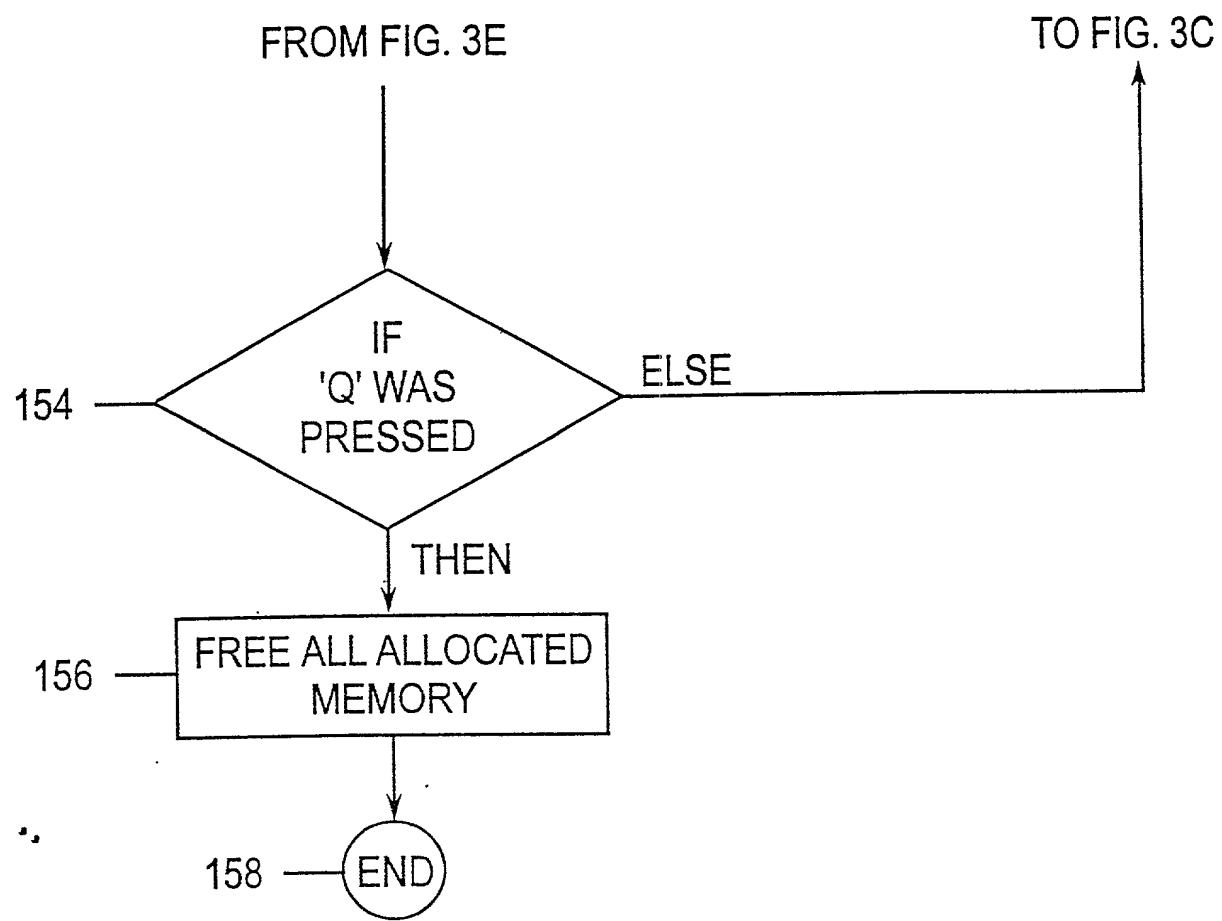


FIG. 4

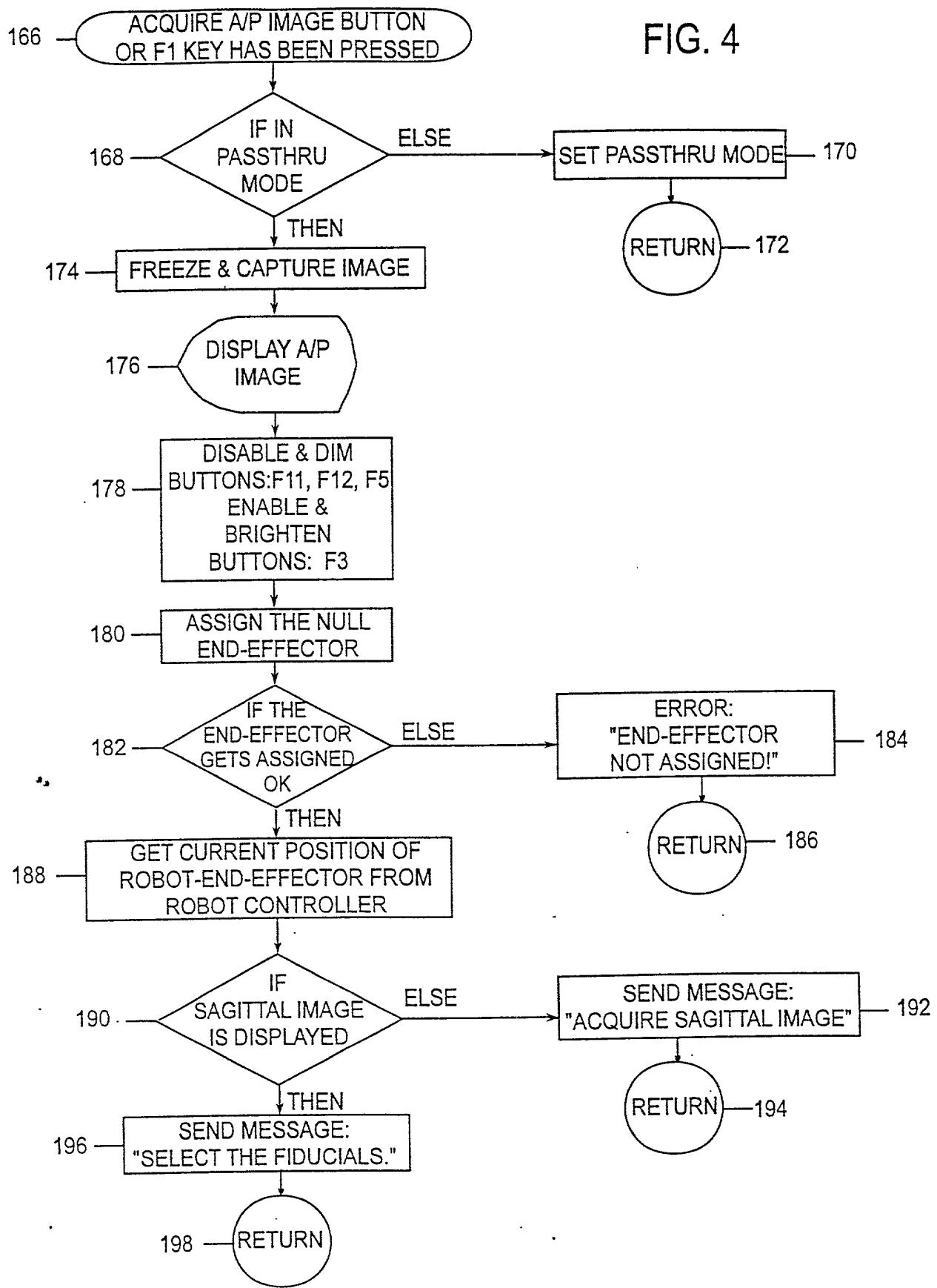


FIG. 5A

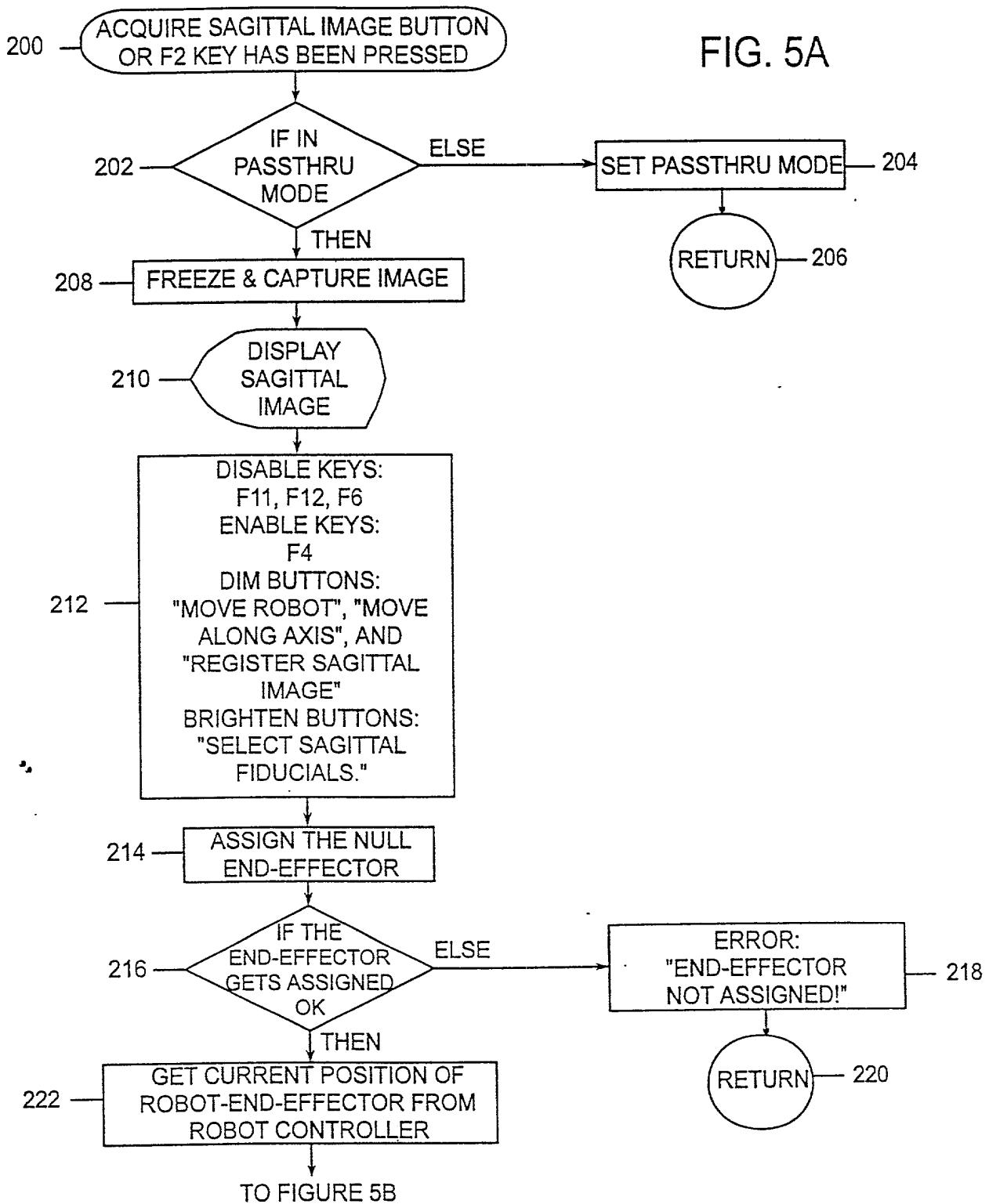


FIG. 5B

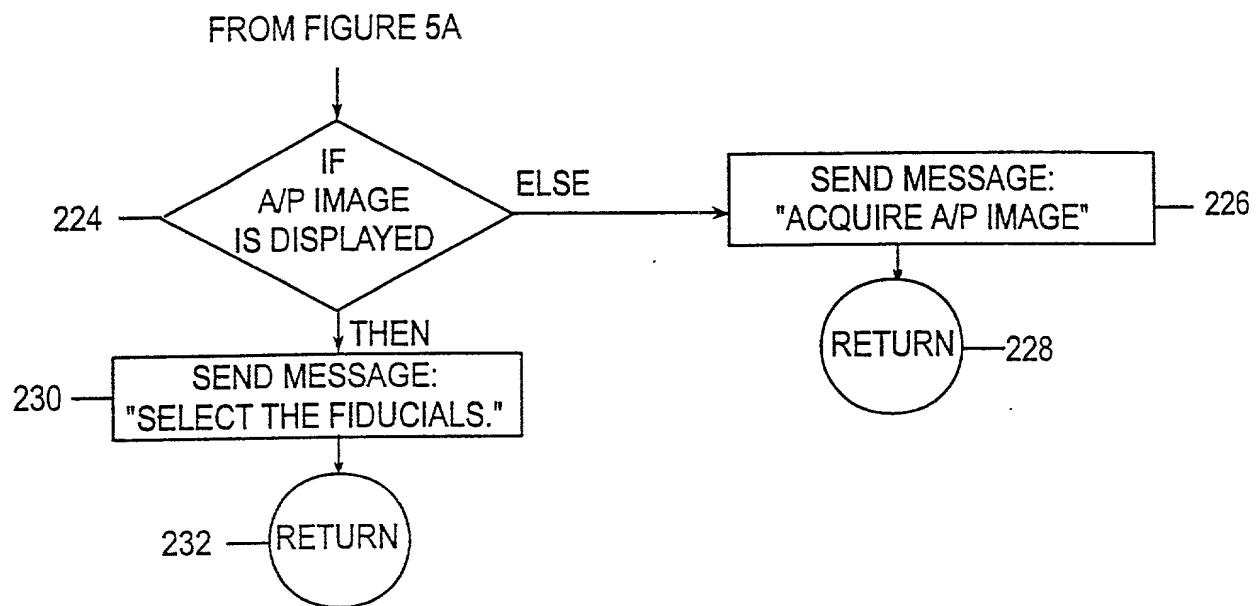
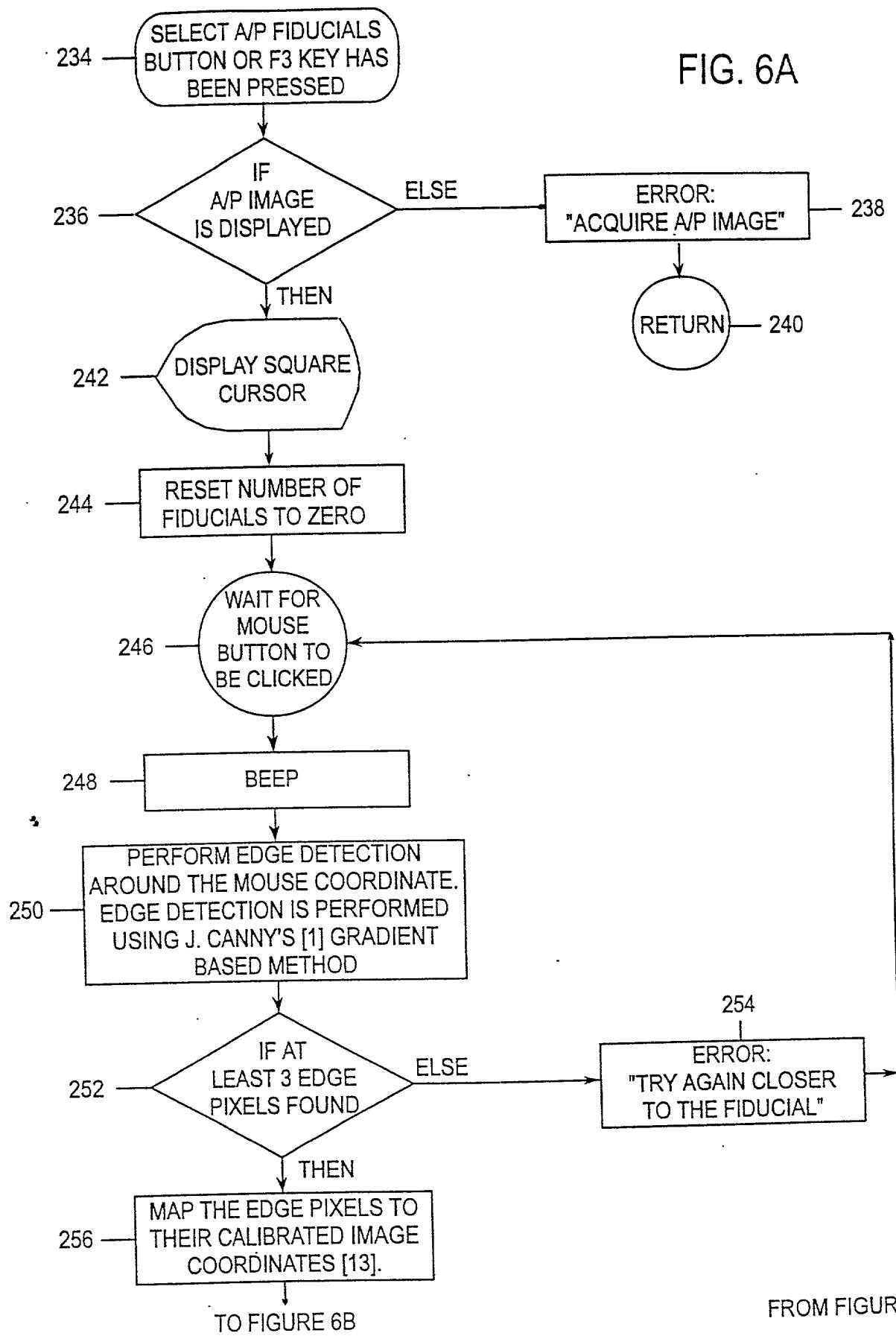


FIG. 6A



FROM FIGURE 6B

FIG. 6B

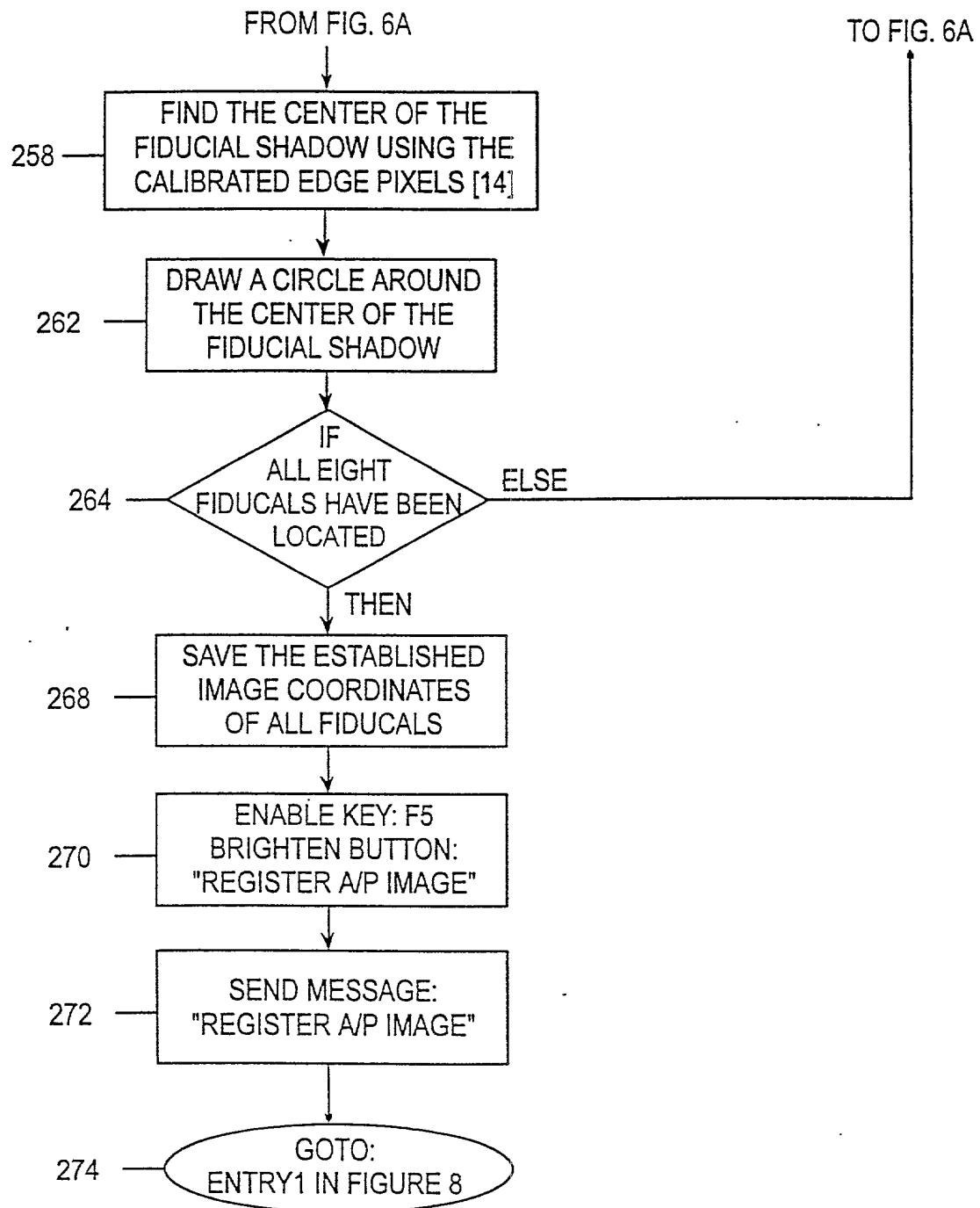
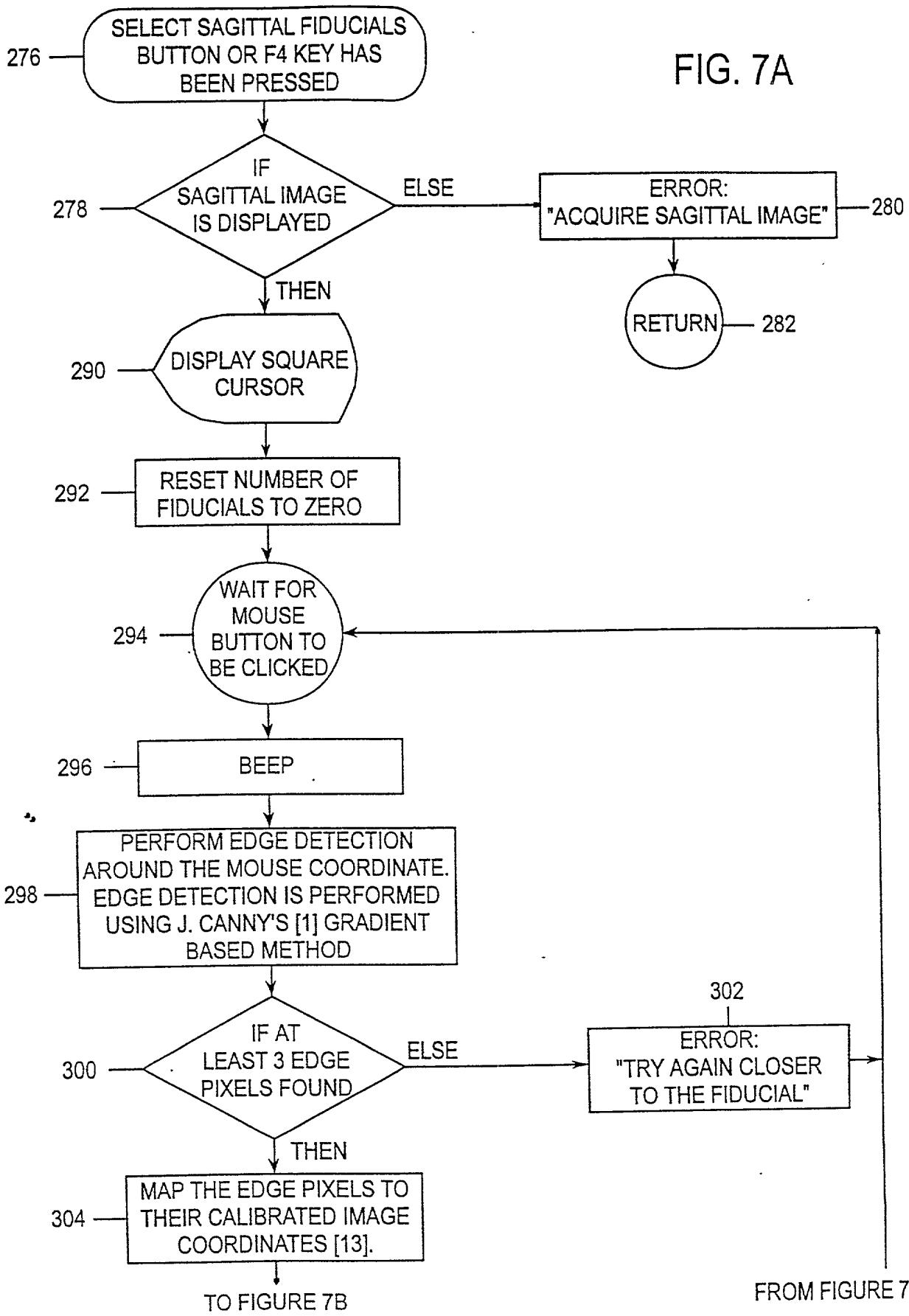


FIG. 7A



FROM FIGURE 7B

FIG. 7B

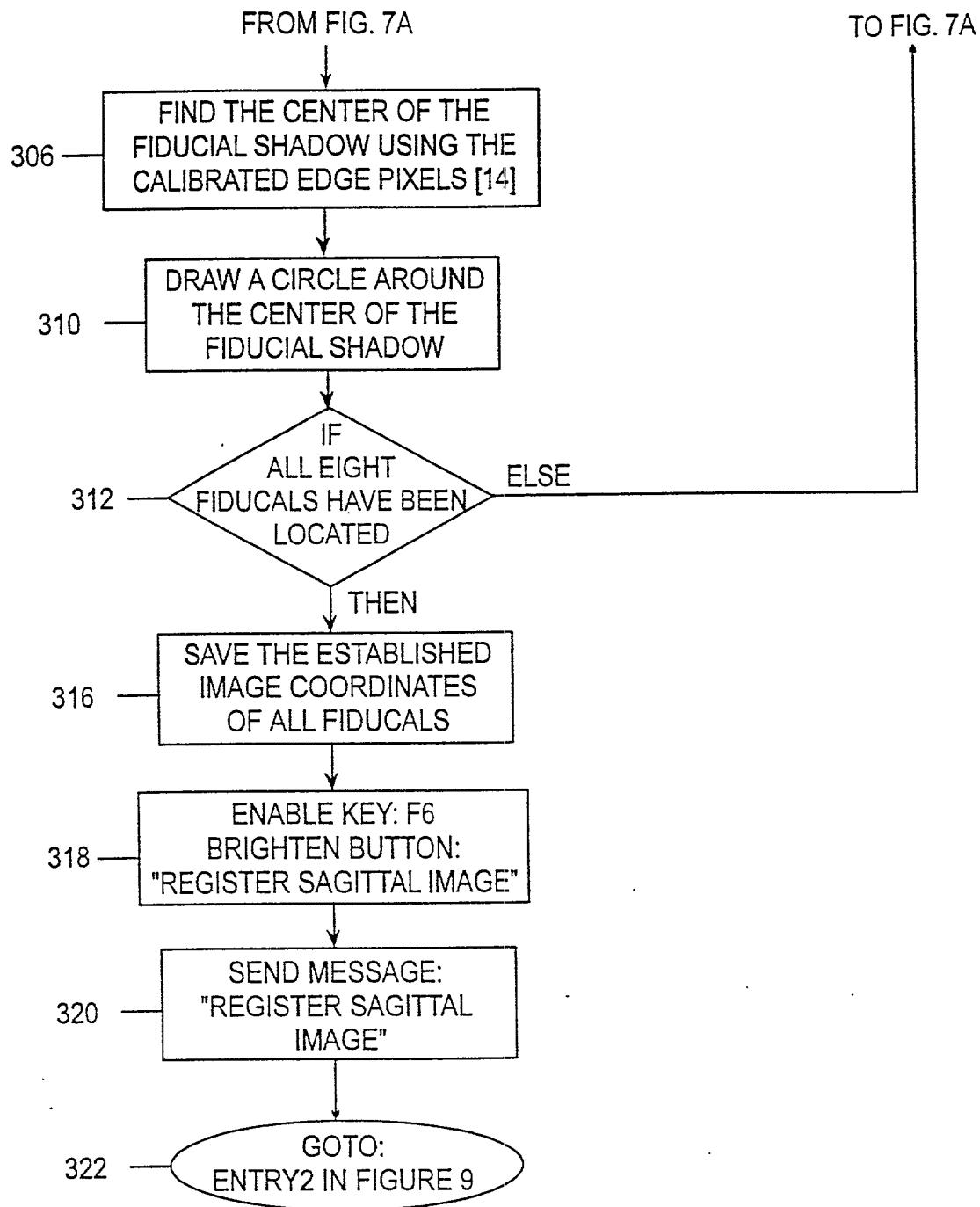


FIG. 8

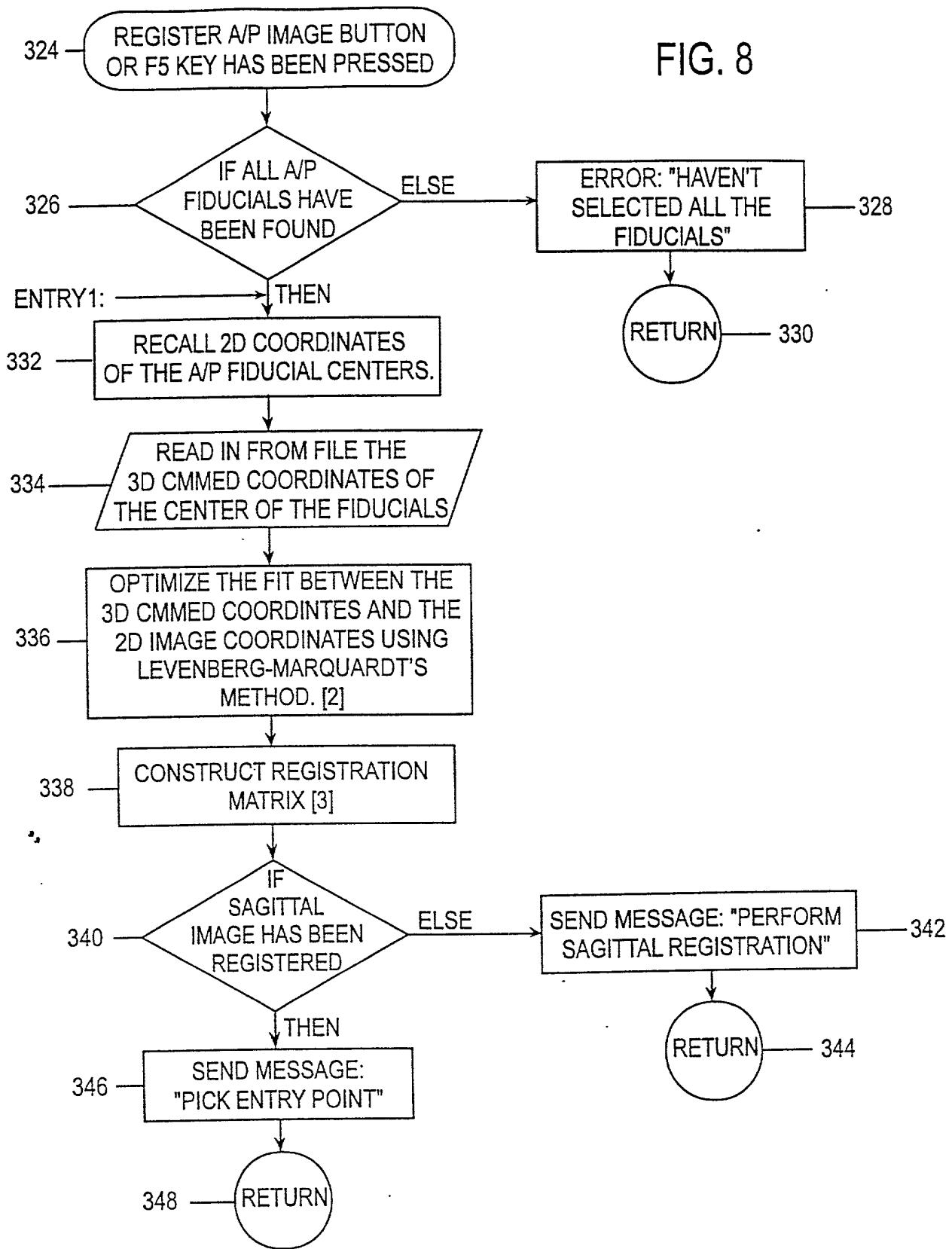


FIG. 9

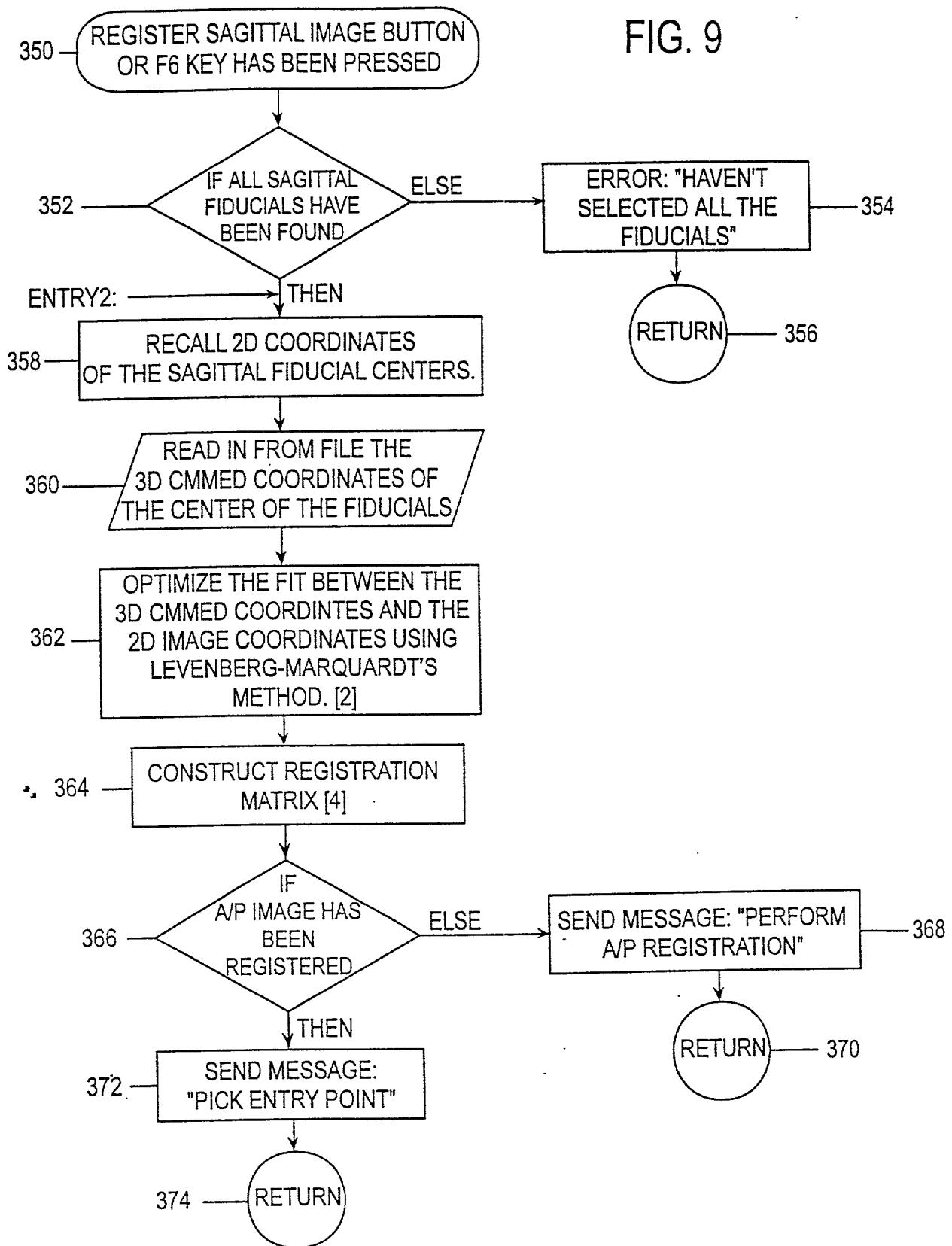


FIG. 10

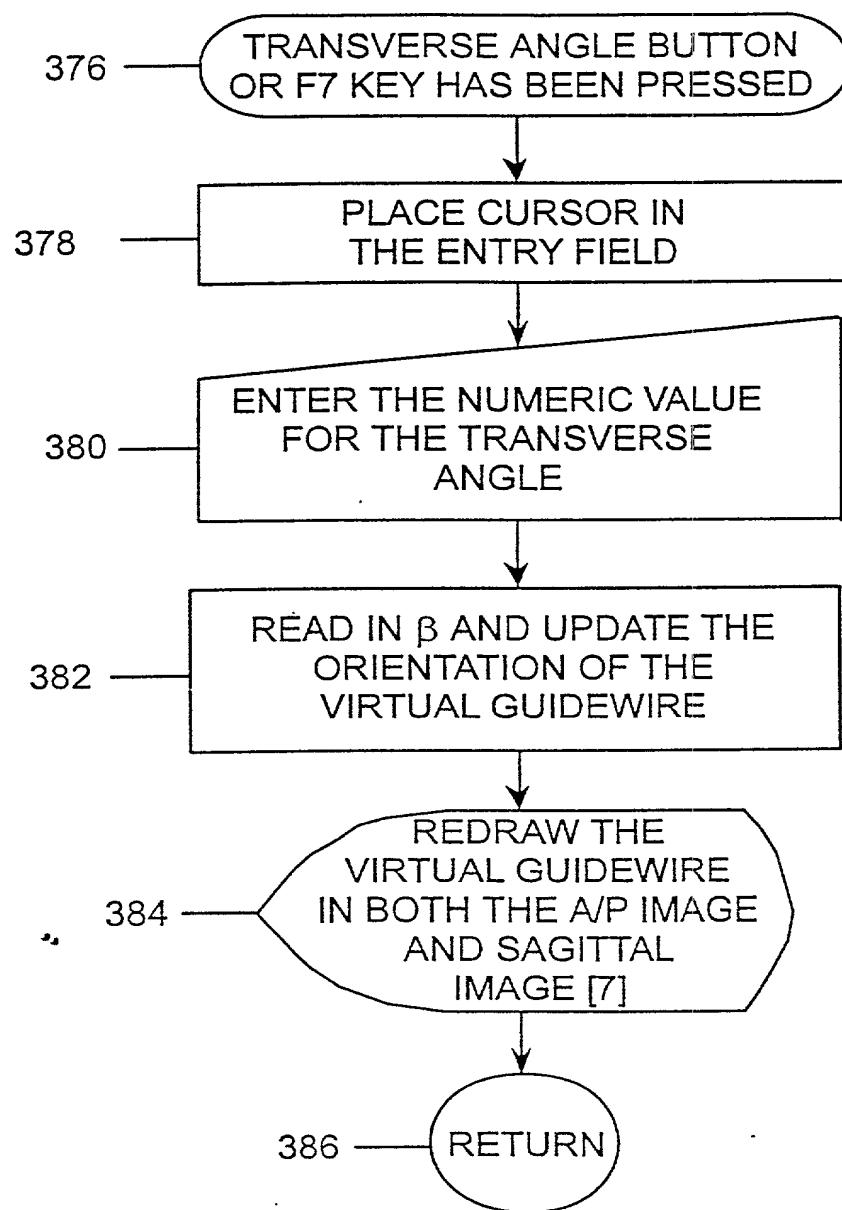


FIG. 11

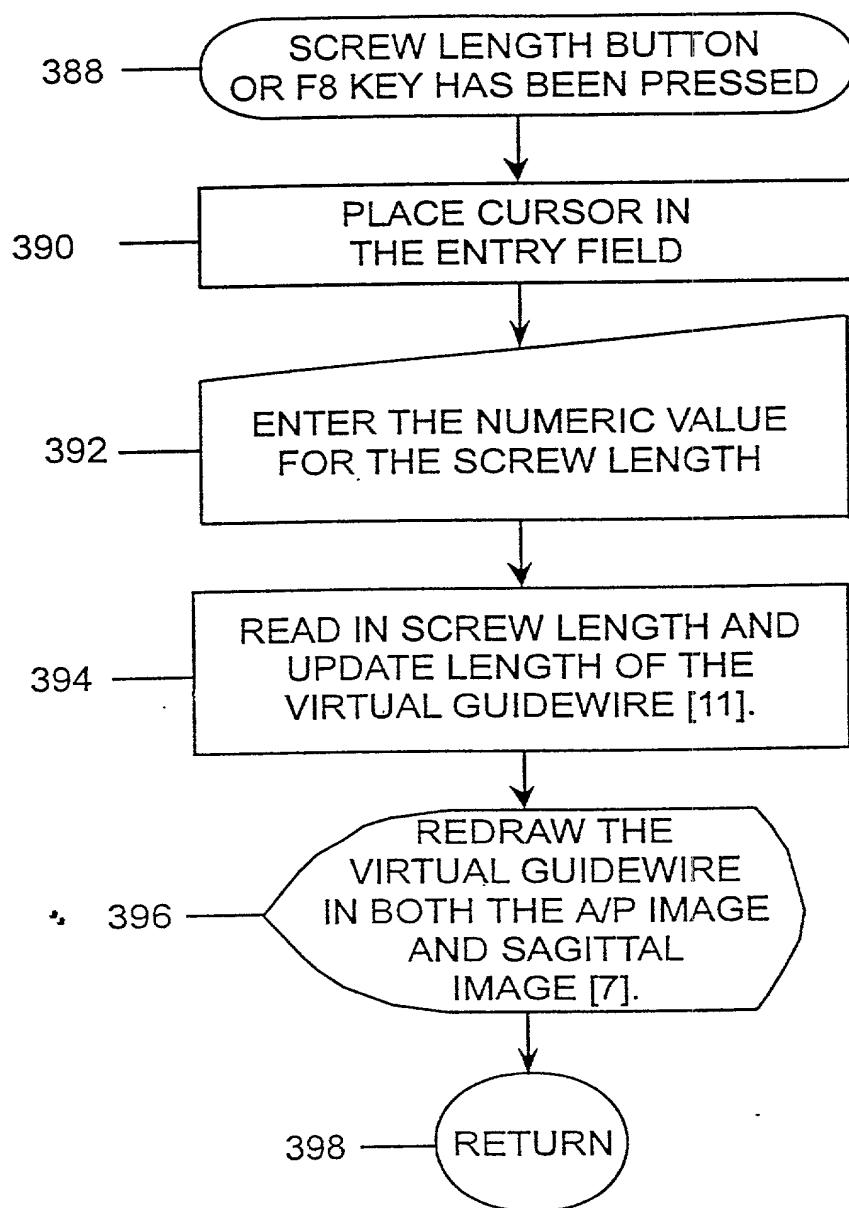


FIG. 12

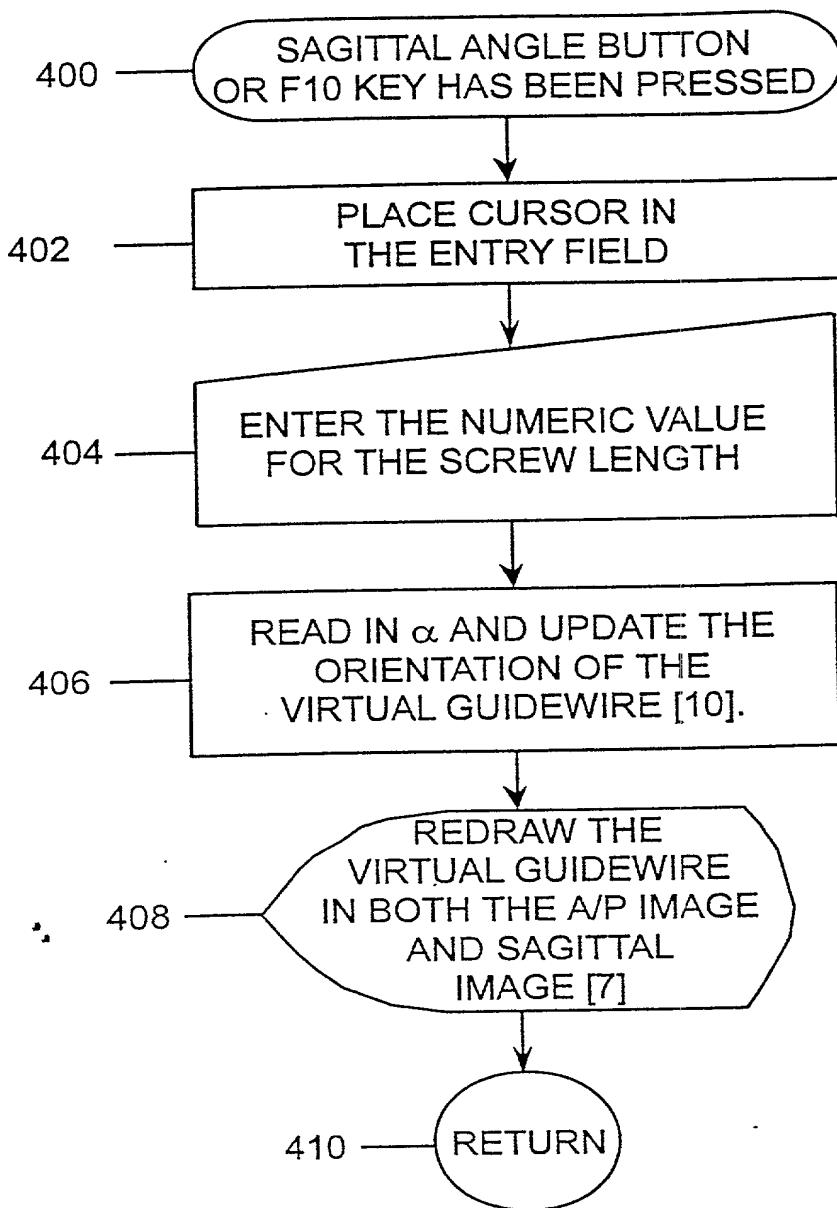


FIG. 13

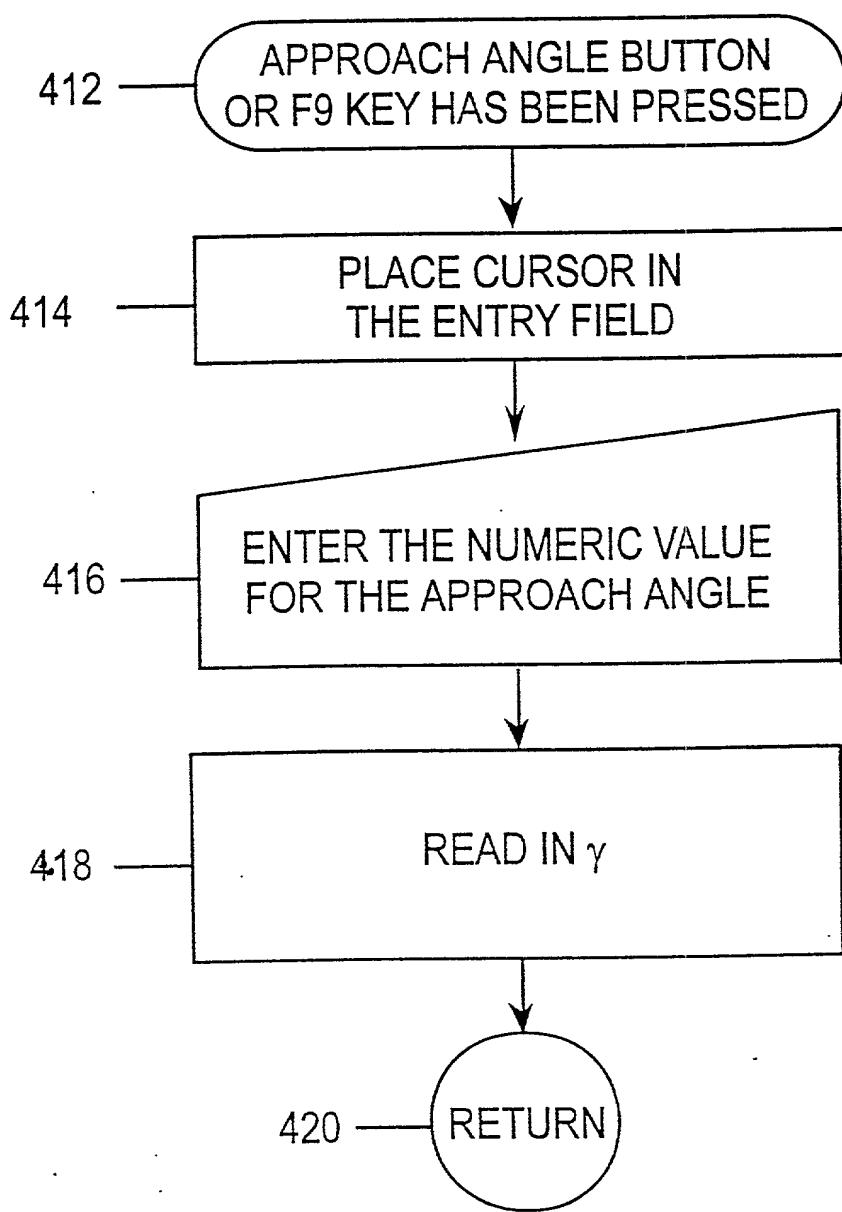


FIG. 14

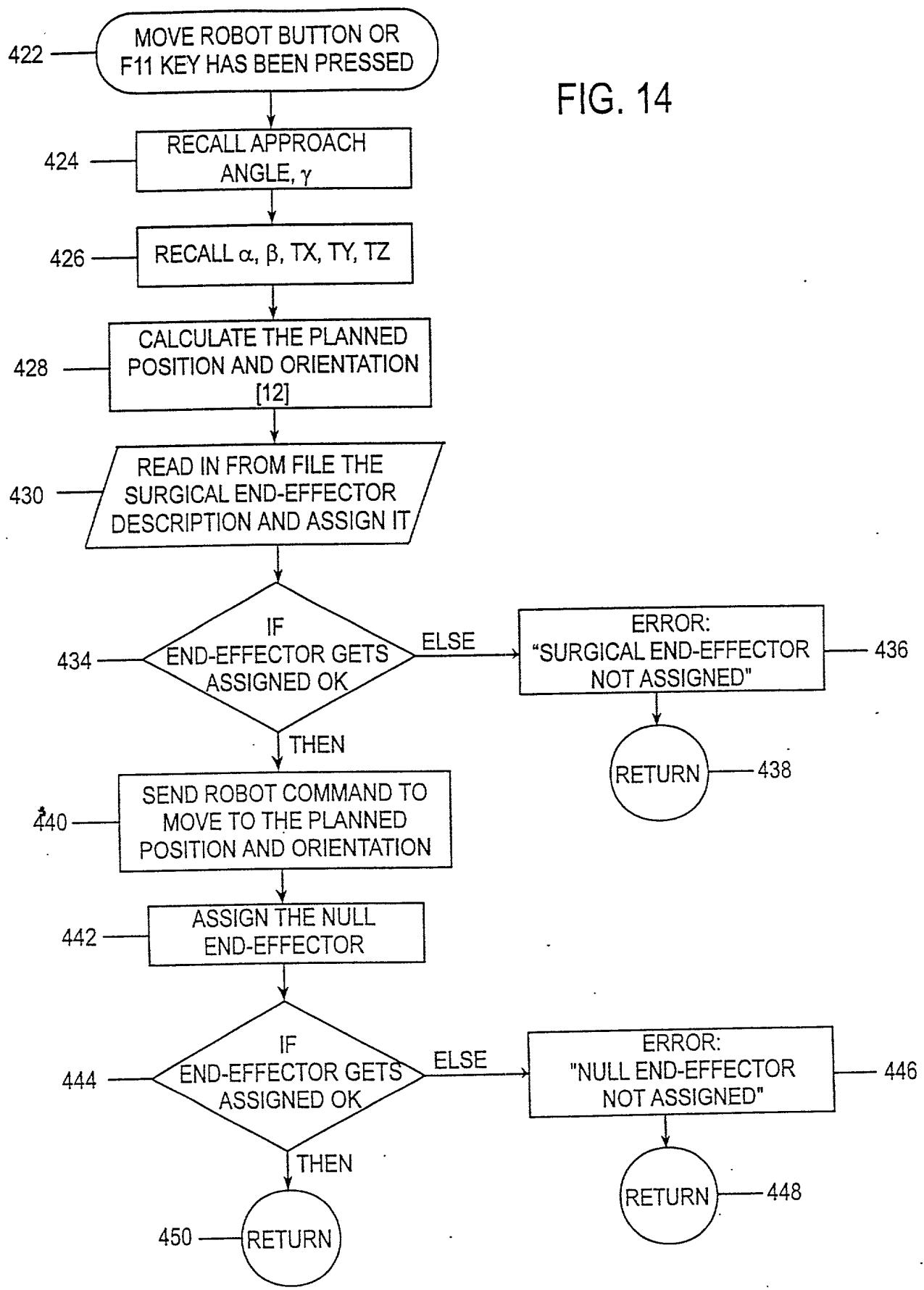


FIG. 15

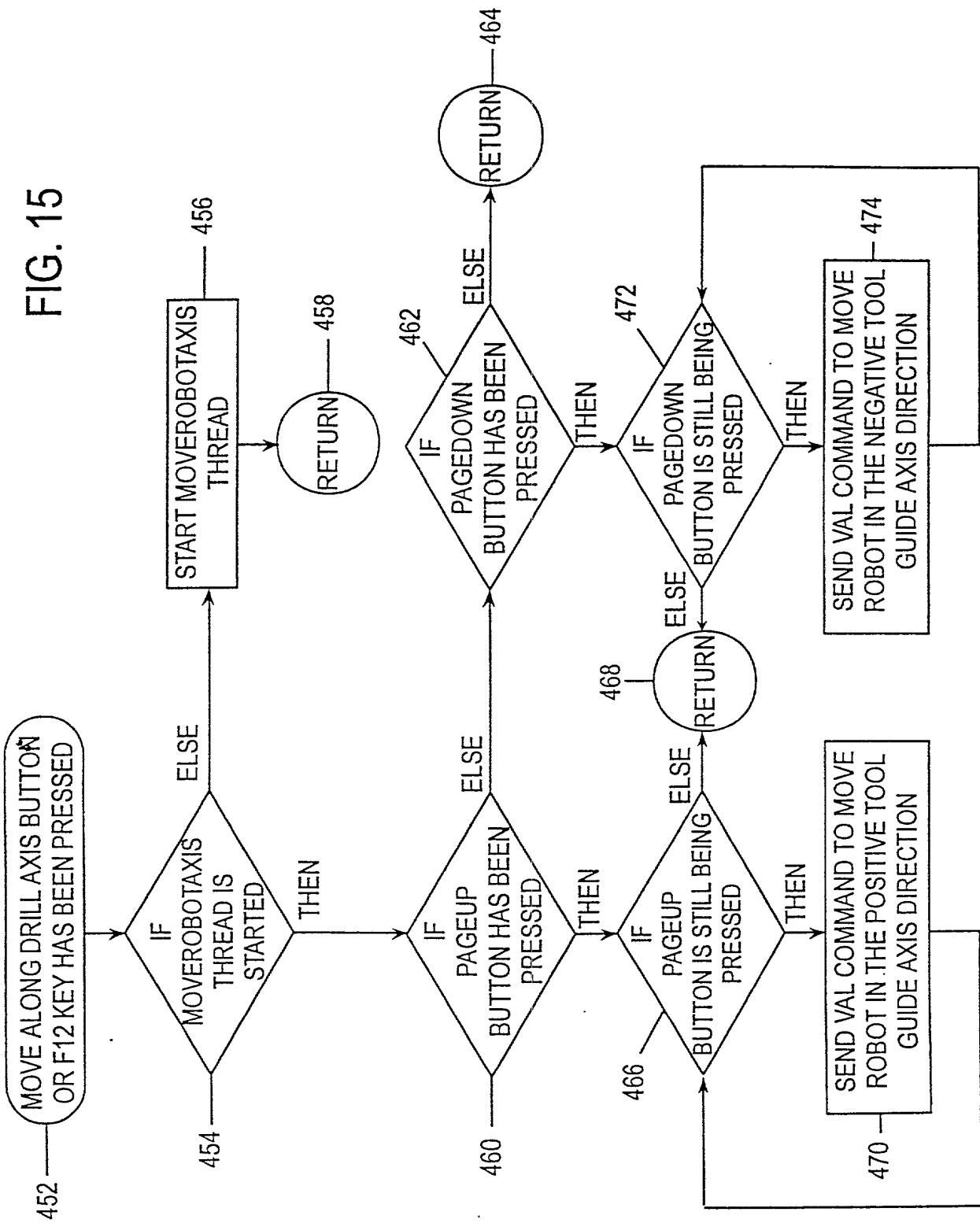


FIG. 16A

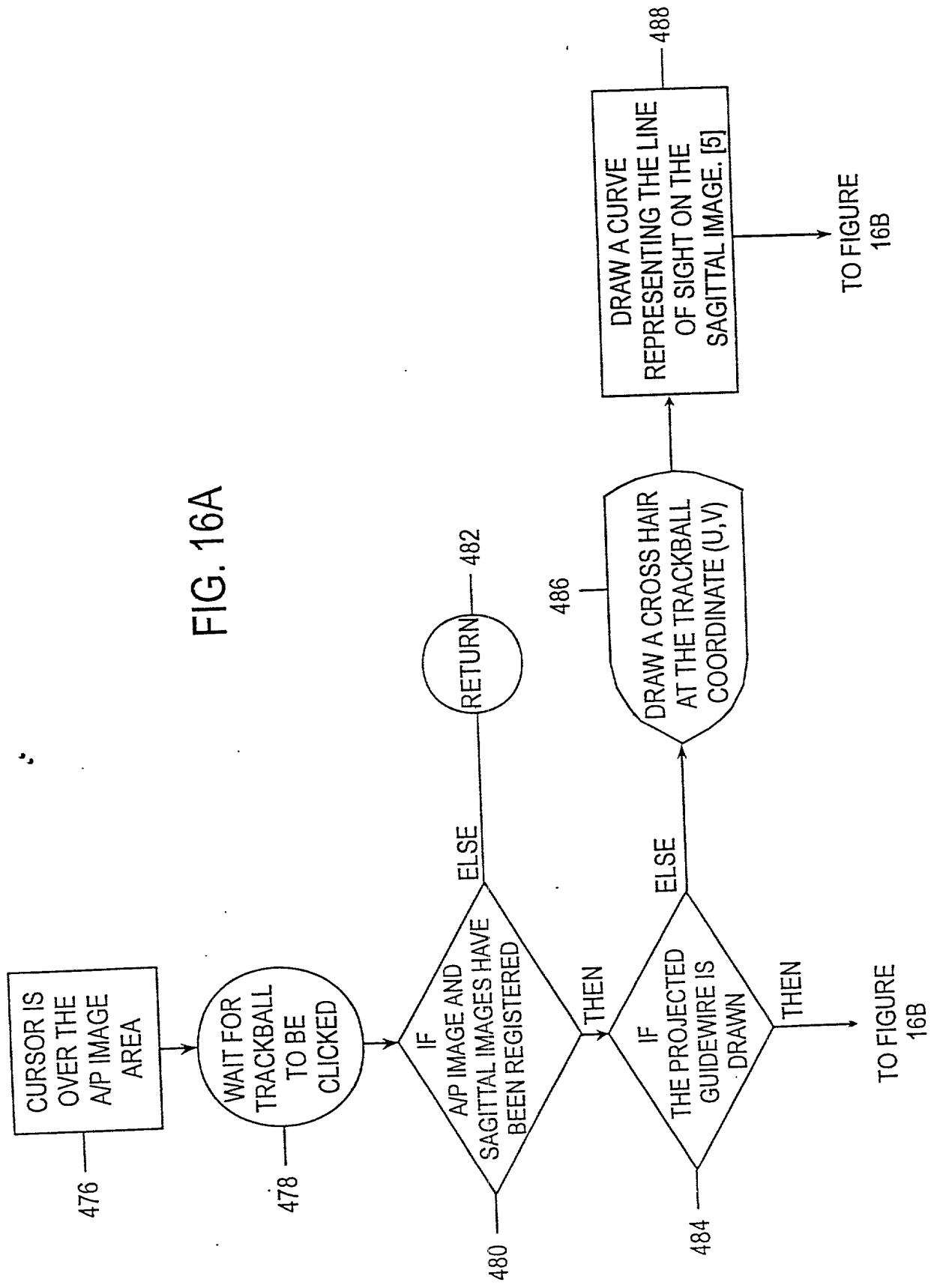


FIG. 16B

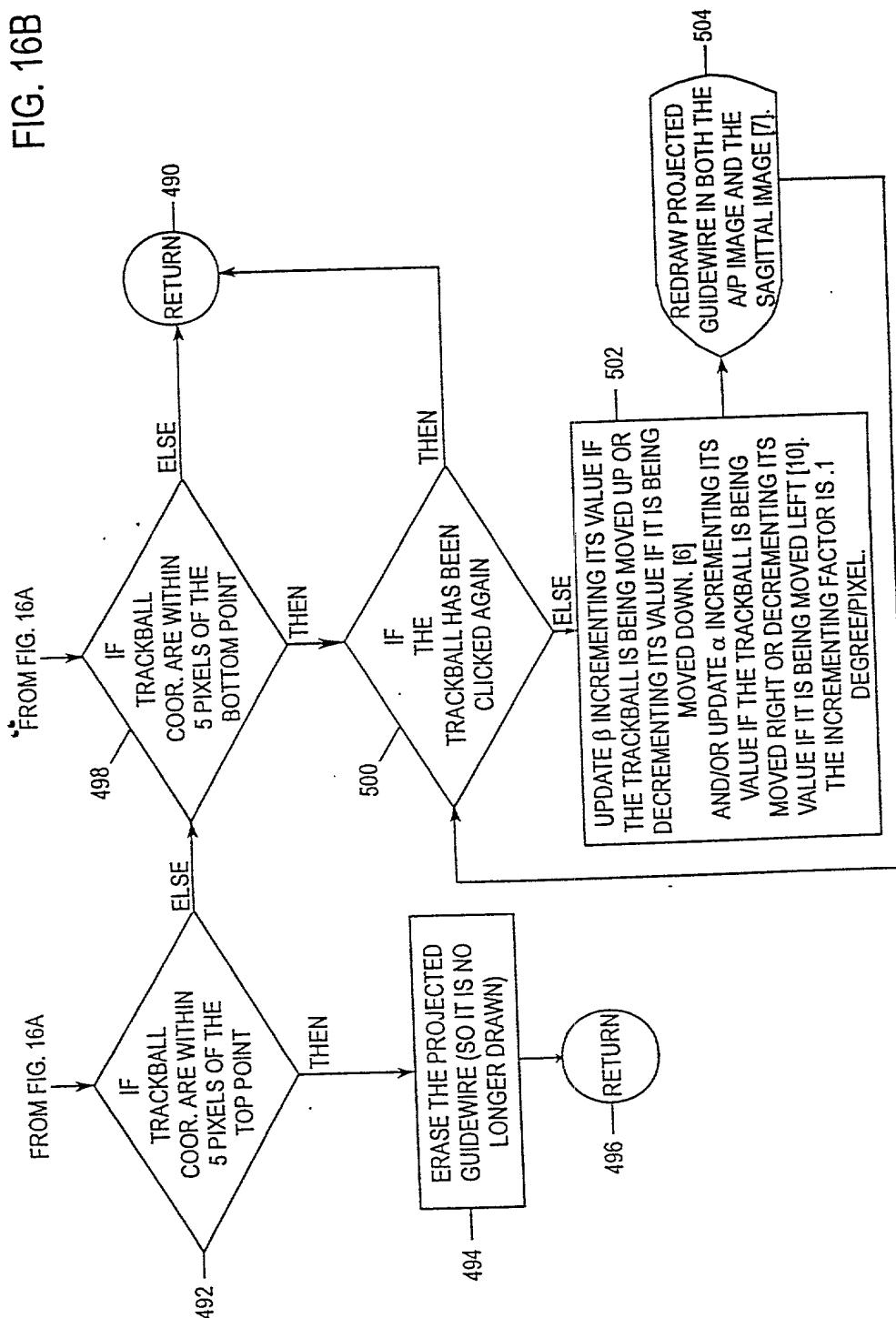
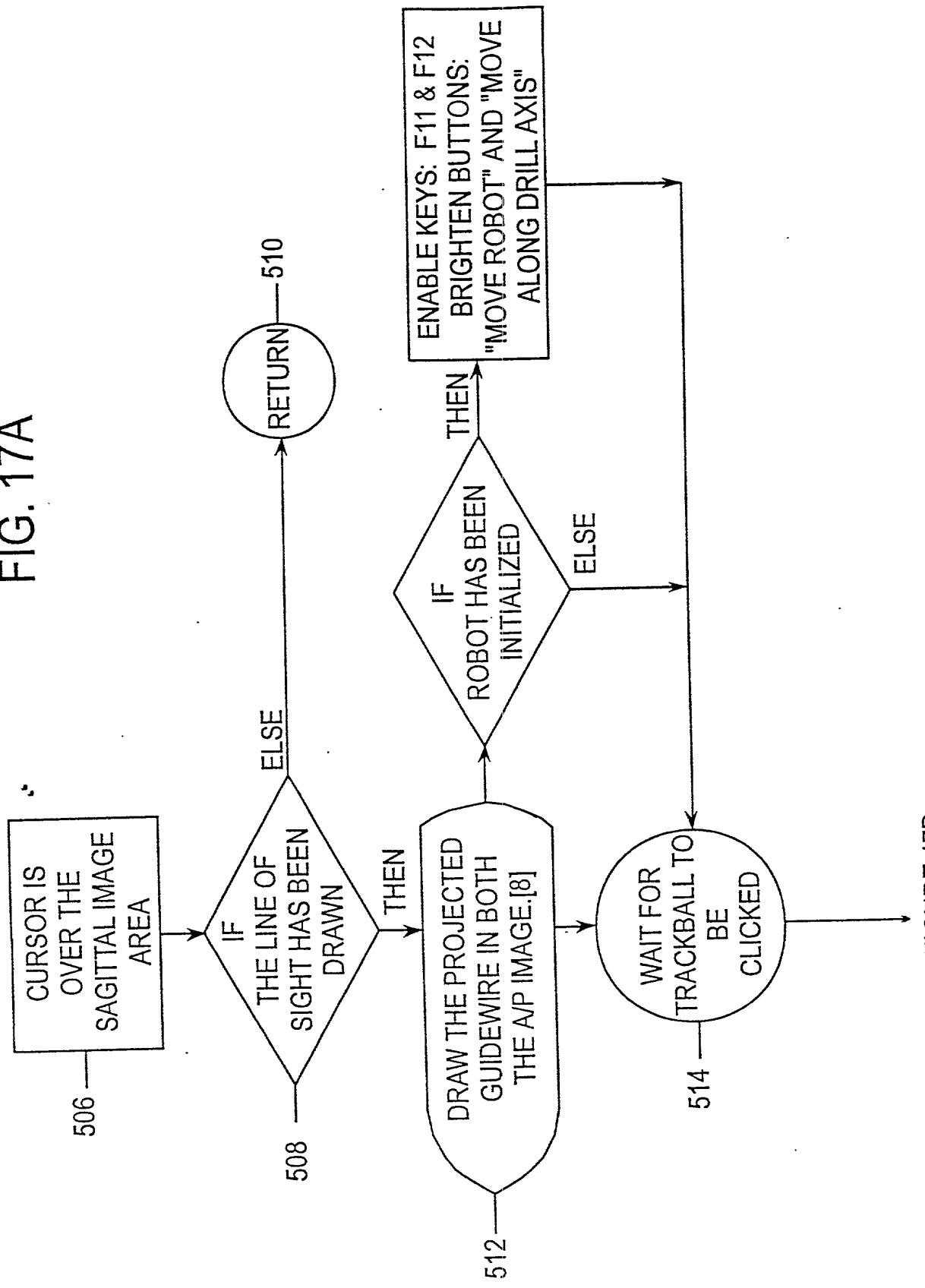


FIG. 17A



TO FIGURE 17B

FIG. 17B

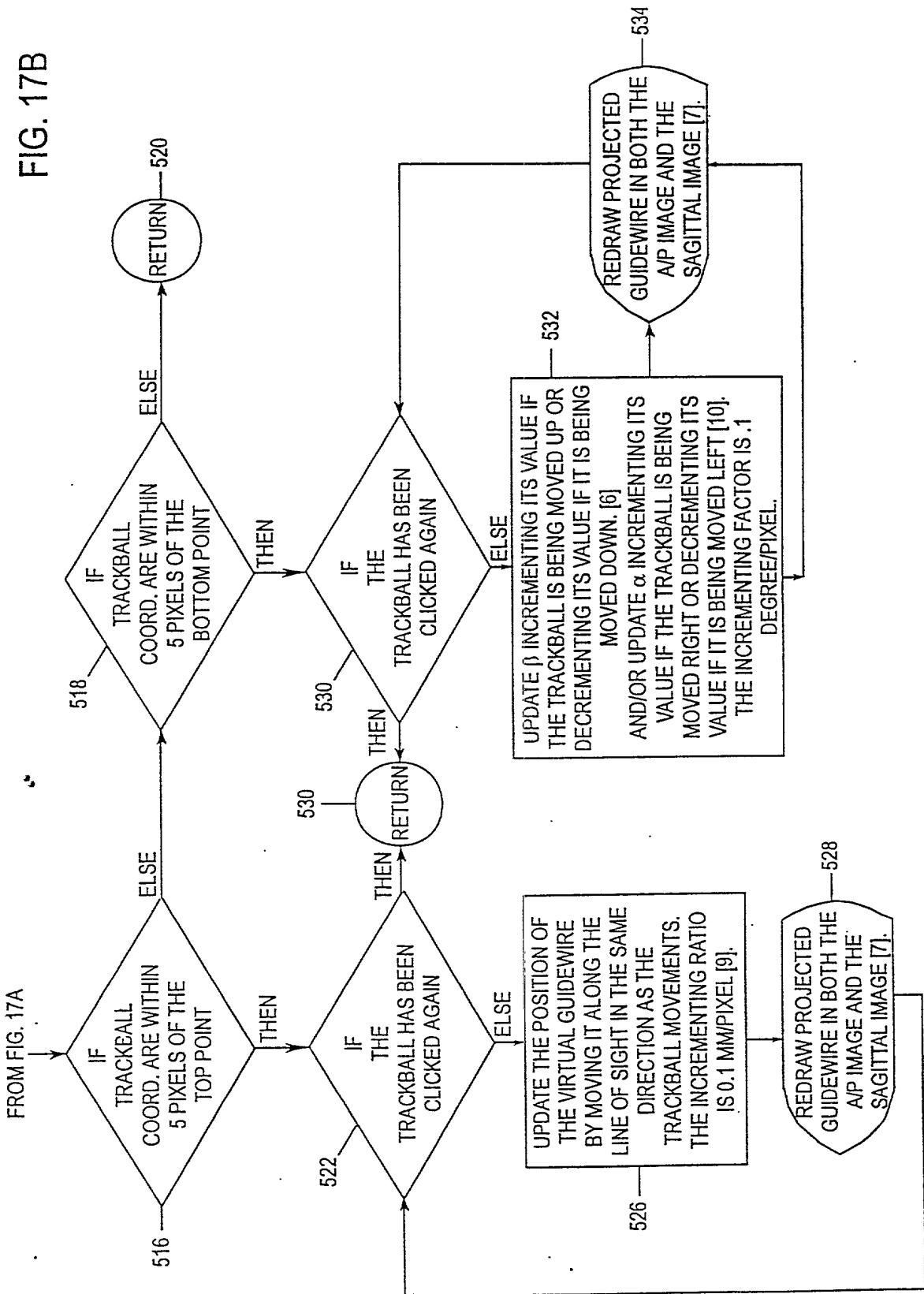
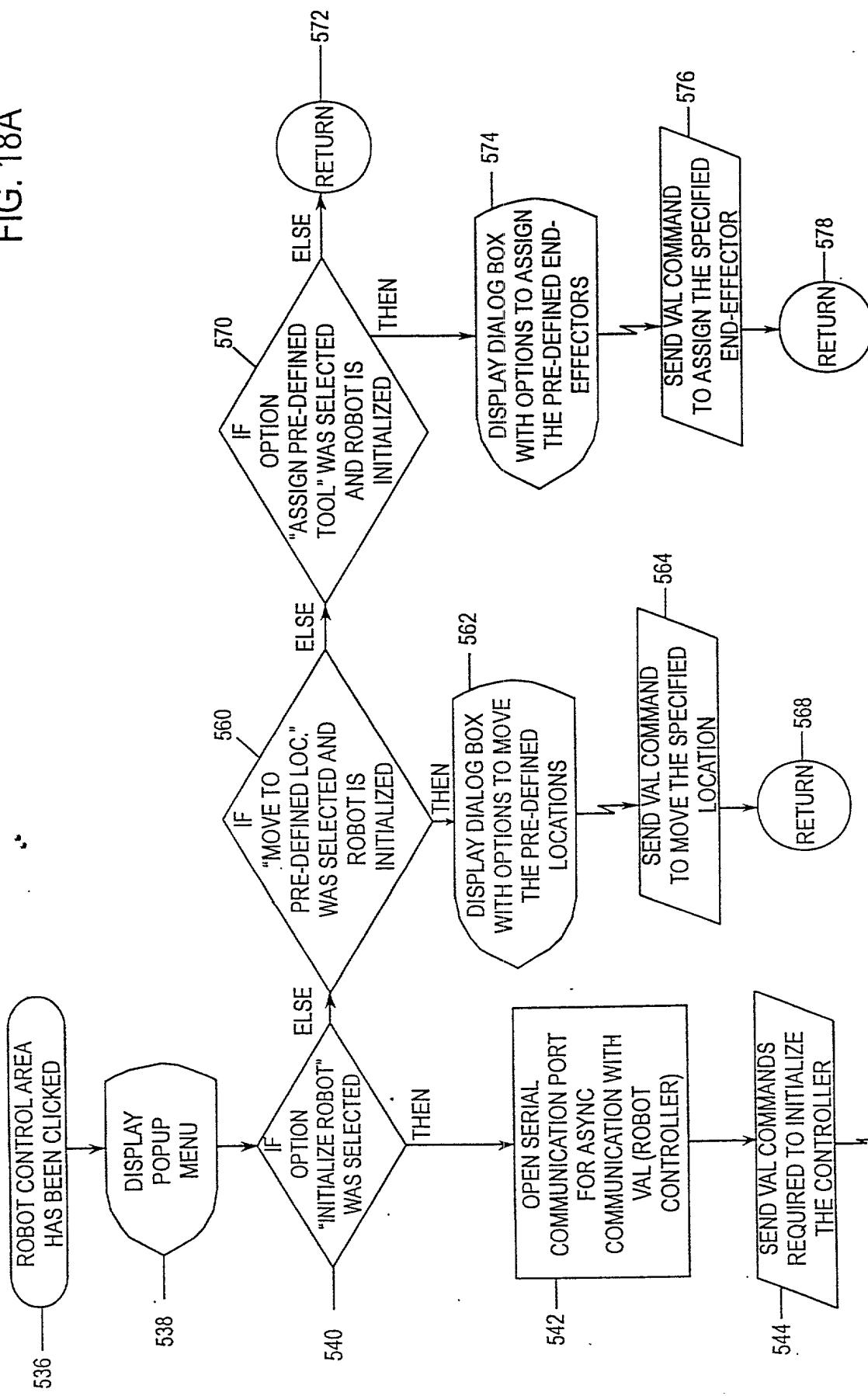
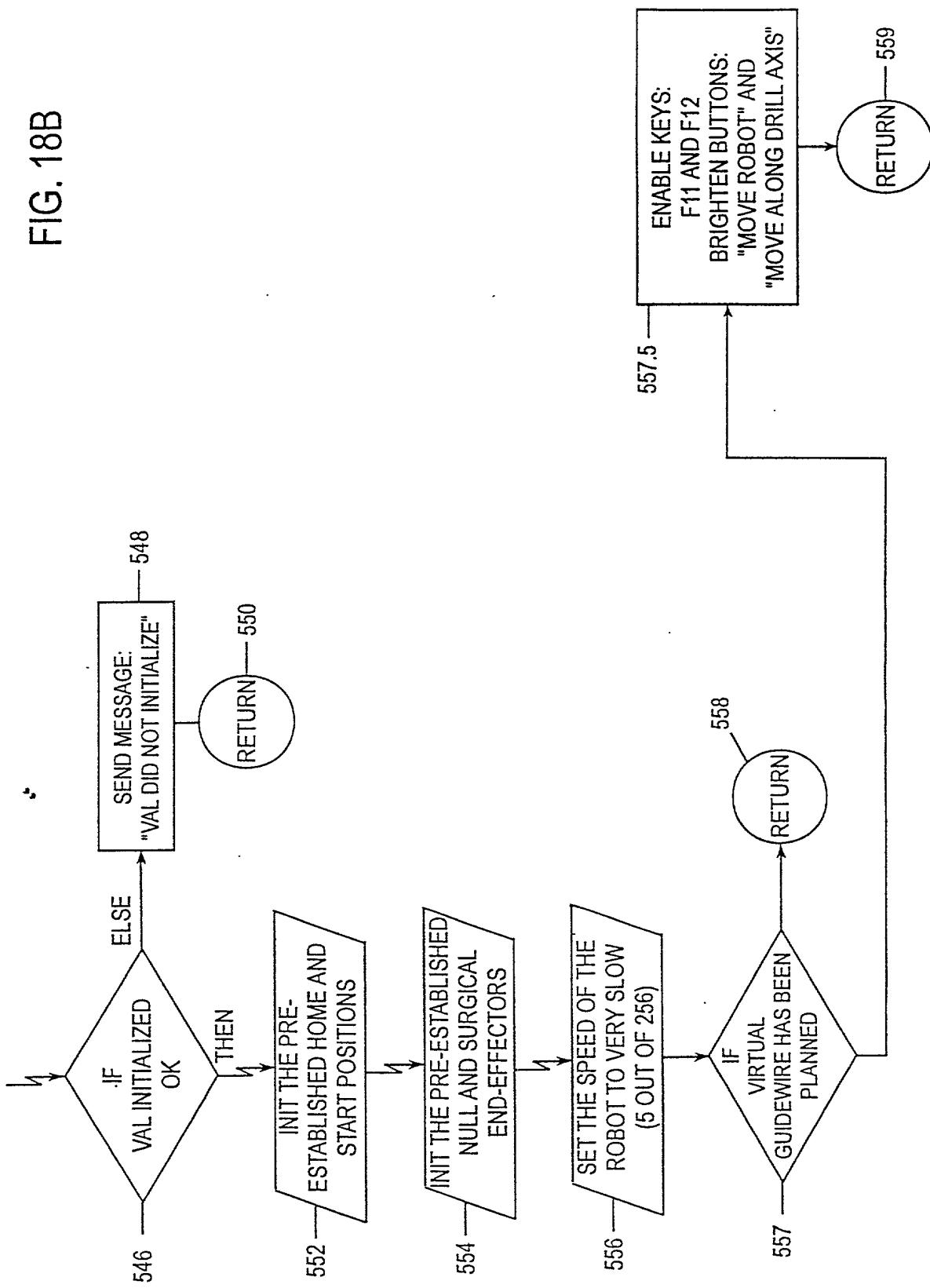


FIG. 18A



TO FIGURE 18B

FIG. 18B



SUPPLEMENTAL DECLARATION AND POWER OF ATTORNEY -- PATENT APPLICATION

As a below named inventor, I hereby declare that I believe I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought in the application entitled:

**APPARATUS AND METHOD FOR PLANNING A STEREOTACTIC SURGICAL
PROCEDURE USING COORDINATED FLUOROSCOPY**

specification of which

(check one) _____ is attached hereto

was filed on May 17, 1996 _____ as

United States Application Serial No. 08/649,798 _____ or

PCT International Application No. _____

and was amended on _____

(if applicable)

I hereby declare that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to herein.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate on which priority is claimed (as listed below) and I have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(b) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>08/648,313</u> (Application Serial No.)	<u>May 15, 1996</u> (Filing Date)	<u>Abandoned</u> (Status-patented, pending, abandoned)

I hereby appoint William R. Coffey, Reg. No. 24023; Jerry E. Hyland, Reg. No. 20904; Richard D. Conard, Reg. No. 27321; Steven R. Lammert, Reg. No. 27653; Richard A. Rezek, Reg. No. 30796; Timothy E. Niednagel, Reg. No. 33266; Perry Palan, Reg. No. 26213; Mark M. Newman, Reg. No. 31472; Bobby B. Gillenwater, Reg. No. 31105; Paul B. Hunt, Reg. No. 37154; John P. Breen, Reg. No. 38833; Jill L. Werling, Reg. No. 39874, and Nancy J. Harrison, Reg. No. 27083, as attorneys of

record with full power of substitution and revocation, to prosecute this application, and to transact all business in the Patent and Trademark Office connected therewith, and I specify that communications regarding the application be directed to:

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11 South Meridian Street
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Telephone (317) 638-1313

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Date

Additional inventors to be similarly identified on attached sheet.